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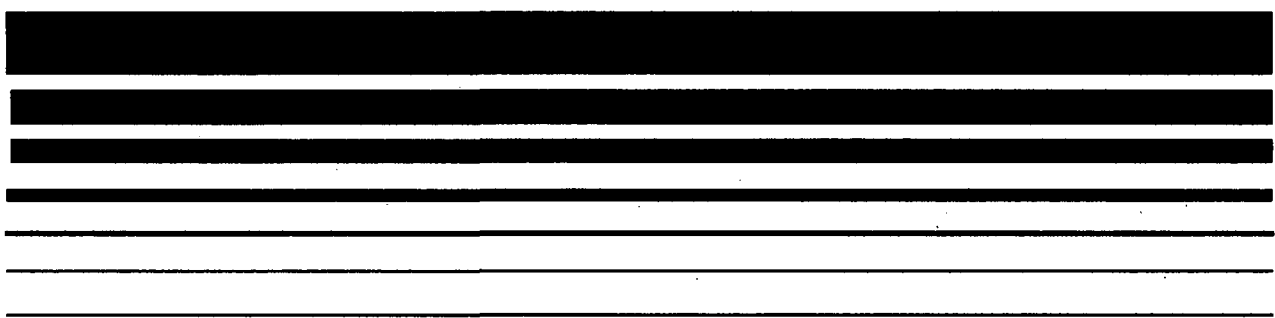
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Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations

DRAFT EIS

Background Information for Proposed Standards



NESHAP

**ETHYLENE OXIDE EMISSIONS FROM COMMERCIAL
STERILIZATION/FUMIGATION OPERATIONS --**

**BACKGROUND INFORMATION FOR PROPOSED
STANDARDS**

Final

ETHYLENE OXIDE EMISSIONS FROM COMMERCIAL STERILIZATION/FUMIGATION
OPERATIONS -- BACKGROUND INFORMATION FOR PROPOSED STANDARDS

Emission Standards Division

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Air and Radiation
Office of Air Quality Planning and Standards
Research Triangle Park, North Carolina 27711

March 1993

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ENVIRONMENTAL PROTECTION AGENCY

Background Information
and Draft
Environmental Impact Statement
for Commercial Sterilization/Fumigation Operations

Prepared by:


7. Bruce Jordan6-7-93

(Date)

Director, Emission Standards Division
U.S. Environmental Protection Agency
Research Triangle Park, North Carolina 27711

1. The proposed national emission standard would limit emissions of ethylene oxide from existing and new commercial sterilization/fumigation operations. The proposed standards implement Section 112 of the Clean Air Act as amended in 1990 and are based on the Administrator's determination of July 16, 1992 (57 FR 31576) that commercial sterilization sources generate a large amount of ethylene oxide, a hazardous air pollutant listed in Section 112(b) of the Act.
2. Copies of this document have been sent to the following Federal Departments: Labor, Health and Human Services, Defense, Transportation, Agriculture, Commerce, Interior, and Energy; the National Science Foundation; the Council on Environmental Quality; members of the State and Territorial Air Pollution Program Administrators; the Association of Local Air Pollution Control Officials; EPA Regional Administrators; Office of Management and Budget; and other interested parties.
3. The comment period for review of this document is 60 days. Mr. David Markwordt, Chemicals and Petroleum Branch, telephone (919) 541-0837, may be contacted regarding the date of the comment period.
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TABLE OF CONTENTS

	<u>Page</u>
LIST OF FIGURES	x
LIST OF TABLES	xi
CHAPTER 1. SUMMARY	1-1
1.1 STATUTORY AUTHORITY	1-1
1.2 REGULATORY ALTERNATIVES	1-1
1.3 ENVIRONMENTAL IMPACT	1-2
1.4 COST IMPACT	1-2
1.5 ECONOMIC IMPACT	1-2
CHAPTER 2. INTRODUCTION	2-1
2.1 BACKGROUND AND AUTHORITY FOR STANDARDS	2-1
2.2 SELECTION OF POLLUTANTS AND SOURCE CATEGORIES	2-5
2.3 PROCEDURE FOR DEVELOPMENT OF NESHAP	2-6
2.4 CONSIDERATION OF COSTS	2-9
2.5 CONSIDERATION OF ENVIRONMENTAL IMPACTS	2-10
2.6 RESIDUAL RISK STANDARDS	2-11
CHAPTER 3. ETHYLENE OXIDE STERILIZATION/FUMIGATION PROCESSES AND EMISSIONS	3-1
3.1 BACKGROUND INFORMATION	3-1
3.2 PROCESS DESCRIPTION	3-4
3.2.1 Bulk Sterilization	3-4
3.2.2 Single-Item Sterilization System	3-16
3.2.3 Spice Fumigators	3-18
3.2.4 Library and Museum Fumigators	3-18
3.2.5 Beehive Fumigators	3-19
3.3 EMISSION SOURCES	3-19
3.3.1 Sterilization Chamber Vents	3-21
3.3.2 Sterilization Chamber Vacuum Pump Drains	3-21
3.3.3 Chamber Exhaust Vent	3-21
3.3.4 Aeration Room Vent	3-23
3.3.5 Equipment Leaks	3-23
3.3.6 Storage and Handling	3-23
3.4 EMISSION ESTIMATES	3-23
3.4.1 Commercial Sterilization Facilities	3-23
3.5 CURRENT REGULATIONS	3-27
3.5.1 Occupational Safety and Health Administration Standard	3-27
3.5.2 State Regulations	3-27
3.6 REFERENCES FOR CHAPTER 3	3-29

TABLE OF CONTENTS (continued)

	<u>Page</u>
CHAPTER 4. EMISSION CONTROL TECHNIQUES	4-1
4.1 BULK STERILIZATION PROCESSES	4-1
4.1.1 Sterilization Chamber Vent Emissions	4-1
4.1.2 Sterilization Chamber Vacuum Pump Drain Emissions	4-16
4.1.3 Chamber Exhaust Emissions	4-18
4.1.4 Aeration Room Vent Emissions	4-20
4.2 OTHER STERILIZATION PROCESSES	4-25
4.2.1 Single-Item Sterilization	4-25
4.2.2 Fumigation with Portable Units	4-25
4.3 ALTERNATIVES TO EO STERILIZATION	4-26
4.4 RETROFIT CONSIDERATIONS	4-26
4.5 IMPACTS OF CFC REGULATION ON EO EMISSION CONTROLS	4-27
4.6 REFERENCES FOR CHAPTER 4	4-27
CHAPTER 5. REGULATORY ALTERNATIVES	5-1
5.1 INTRODUCTION	5-1
5.2 REGULATORY ALTERNATIVES	5-2
CHAPTER 6. ENVIRONMENTAL IMPACTS	6-1
6.1 AIR POLLUTION IMPACTS	6-1
6.1.1 Baseline Emissions and Emission Reduction	6-1
6.1.2 Secondary Impacts	6-1
6.2 WATER QUALITY IMPACTS	6-3
6.3 SOLID WASTE IMPACTS	6-4
6.4 ENERGY IMPACTS	6-4
6.5 OTHER ENVIRONMENTAL CONCERNS	6-6
6.5.1 Irreversible and Irretrievable Commitment of Resources	6-6
6.5.2 Environmental Impact of Delayed Standards	6-6
6.6 REFERENCES FOR CHAPTER 6	6-6
CHAPTER 7. EMISSION CONTROL COSTS	7-1
7.1 STERILIZATION VENT CONTROL COSTS	7-2
7.1.1 Description of Components Costed	7-3
7.1.2 General Assumptions	7-3
7.2 CHAMBER EXHAUST CONTROL COSTS	7-5
7.2.1 Description of Components Costed	7-5
7.2.2 General Assumptions	7-6

TABLE OF CONTENTS (continued)

	<u>Page</u>
7.3 AERATION ROOM CONTROL COSTS	7-6
7.3.1 Description of Components Costed	7-7
7.3.2 General Assumptions	7-7
7.4 RESULTS OF COST ANALYSIS	7-9
7.5 OTHER COST CONSIDERATIONS	7-9
7.6 REFERENCES FOR CHAPTER 7	7-12
 CHAPTER 8. THE ECONOMIC IMPACTS OF THE CANDIDATE NESHAP CONTROLS	 8-1
8.1 INTRODUCTION	8-1
8.2 ETHYLENE OXIDE STERILIZATION	8-2
8.2.1 Process Inputs	8-2
8.3 SUBSTITUTION POSSIBILITIES AND THE PRICE ELASTICITY OF DEMAND	8-3
8.4 SUPPLY OF EO STERILIZATION SERVICES	8-4
8.4.1 National Summary of Ethylene Oxide Sterilization	8-5
8.4.2 Industry Groups Supplying EO Sterilization Services	8-7
8.5 DEMAND FOR ETHYLENE OXIDE STERILIZATION SERVICES	8-34
8.6 ECONOMIC EFFECTS OF CANDIDATE NESHAP CONTROLS UNDER THREE CONTROL OPTIONS	8-35
8.6.1 The Three Control Options	8-35
8.6.2 Theoretical Framework for Economic Impact Analysis	8-36
8.6.3 Analytical Procedure	8-42
8.6.4 Results	8-48
8.7 EFFECTS OF THE REGULATION ON SMALL BUSINESSES	8-59
8.7.1 Requirements of the Regulatory Flexibility Act	8-59
8.7.2 Small Businesses Performing Ethylene Oxide Sterilization	8-61
8.7.3 Small Businesses in the Contract Sterilizer Industry Group	8-62
8.7.4 Substitution of Contract Sterilization for In-House Sterilization	8-63
8.7.5 Small Business Impacts in Other Industry Groups	8-70
8.7.6 Summary	8-72
8.8 CONCLUSIONS	8-72
8.8.1 Effects on Existing Facilities	8-72
8.8.2 Effects on New Facilities	8-77
8.9 REFERENCES FOR CHAPTER 8	8-78

TABLE OF CONTENTS (continued)

	<u>Page</u>
APPENDIX A EVOLUTION OF THE BACKGROUND INFORMATION DOCUMENT	A-1
APPENDIX B INDEX TO ENVIRONMENTAL CONSIDERATIONS	B-1
APPENDIX C EMISSION SOURCE TEST DATA	C-1
APPENDIX D EMISSION MEASUREMENT AND CONTINUOUS MONITORING	D-1
APPENDIX E SUPPLEMENTAL INFORMATION FOR THE COST ANALYSIS	E-1

LIST OF FIGURES

	<u>Page</u>
Figure 3-1. Schematic of a gas sterilizer	3-6
Figure 3-2. Sterilization cycle for 12/88	3-12
Figure 3-3. Sterilization cycle for pure EO	3-13
Figure 3-4. Schematic of emission sources at commercial sterilization facilities	3-20
Figure 3-5. Hydrolysis rates of dilute, neutral aqueous solutions of ethylene oxide	3-22
Figure 4-1. Countercurrent packed scrubbing system	4-5
Figure 4-2. Detoxification tower control system	4-7
Figure 4-3. Catalytic oxidation system	4-11
Figure 4-4. Condensation/reclamation system	4-14
Figure 4-5a. Once-through liquid-ring vacuum pump	4-17
Figure 4-5b. Recirculating liquid-ring vacuum pump	4-17
Figure 8-1. Demand curve for Commodity Q	8-37
Figure 8-2. Supply curve for Commodity Q	8-38
Figure 8-3. Market equilibrium with and without an upward shift in the supply curve due to ethylene oxide emission controls	8-40
Figure 8-4. The market for contract sterilization without the air emission standard in place	8-64
Figure 8-5. Marginal cost curves for a contract sterilizer and an in-house sterilizer, with and without the air emission standard in effect	8-66
Figure 8-6. The market for contract sterilization with the air emission standard in effect	8-69
Figure C-1. Sampling point locations	C-9

LIST OF TABLES

	<u>Page</u>
TABLE 1-1. POTENTIAL NATIONWIDE PERCENT EMISSION REDUCTION AND NATIONWIDE AIR, WASTEWATER, SOLID WASTE, AND ENERGY IMPACTS	1-3
TABLE 1-2. NATIONWIDE REGULATORY ALTERNATIVE COST IMPACTS	1-4
TABLE 3-1. LOCATIONS OF FACILITIES--EPA COMMERCIAL STERILIZATION DATA BASE	3-3
TABLE 3-2. NUMBER OF FACILITIES AND STANDARD INDUSTRIAL CLASSIFICATION (SIC) PER INDUSTRY CATEGORY-- EPA COMMERCIAL STERILIZATION DATA BASE	3-5
TABLE 3-3. CHAMBER SIZES--EPA COMMERCIAL STERILIZATION DATA BASE	3-7
TABLE 3-4. PHYSICAL AND CHEMICAL PROPERTIES OF ETHYLENE OXIDE, DICHLORODIFLUOROMETHANE, AND CARBON DIOXIDE	3-9
TABLE 3-5. STERILANT GAS TYPE USAGE--EPA COMMERCIAL STERILIZATION DATA BASE	3-10
TABLE 3-6. AVERAGE EMISSIONS FROM COMMERCIAL STERILIZATION FACILITIES--EPA COMMERCIAL STERILIZATION DATA BASE	3-25
TABLE 3-7. STATE REGULATIONS FOR ETHYLENE OXIDE EMISSIONS	3-28
TABLE 4-1. ETHYLENE OXIDE EMISSION CONTROL DEVICES FOR STERILIZER VENTS--EPA COMMERCIAL STERILIZATION DATA BASE	4-2
TABLE 5-1. REGULATORY ALTERNATIVES	5-3
TABLE 6-1. NATIONWIDE AIR IMPACTS	6-2
TABLE 6-2. POTENTIAL NATIONWIDE WASTEWATER, SOLID WASTE, AND ENERGY IMPACTS	6-5
TABLE 7-1. NATIONWIDE REGULATORY ALTERNATIVE COST IMPACTS	7-10
TABLE 7-2. REPRESENTATIVE FACILITY COST IMPACTS	7-11

LIST OF TABLES (continued)

	<u>Page</u>
TABLE 8-1. SUMMARY STATISTICS ON THE USE OF STERILANT GAS AT 188 COMMERCIAL STERILIZATION FACILITIES	8-6
TABLE 8-2. STANDARD INDUSTRIAL CLASSIFICATION CODES FOR 188 COMMERCIAL STERILIZATION FACILITIES .	8-8
TABLE 8-3. RECENT PERFORMANCE AND FORECAST DATA FOR MEDICAL DEVICE SUPPLIERS (SIC 3841 AND 3842) .	8-11
TABLE 8-4. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 62 MEDICAL DEVICE SUPPLIERS	8-13
TABLE 8-5. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 24 OTHER HEALTH-RELATED SUPPLIERS	8-15
TABLE 8-6. RECENT PERFORMANCE AND FORECAST DATA FOR PHARMACEUTICAL MANUFACTURERS (SIC 2834) . . .	8-17
TABLE 8-7. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 39 PHARMACEUTICAL MANUFACTURERS	8-19
TABLE 8-8. RECENT PERFORMANCE DATA FOR SPICE MANUFACTURERS (SIC 2099)	8-21
TABLE 8-9. 1987 PERFORMANCE DATA FOR SPICE MANUFACTURERS (SIC 2099)	8-23
TABLE 8-10. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 23 SPICE MANUFACTURERS . . .	8-24
TABLE 8-11. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 13 MUSEUMS AND LIBRARIES	8-27
TABLE 8-12. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 10 LABORATORIES . .	8-30
TABLE 8-13. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 17 CONTRACT STERILIZERS	8-33
TABLE 8-14. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) UNDER THE THREE CONTROL OPTIONS, FOR AFFECTED INDUSTRY GROUPS	8-50

LIST OF TABLES (continued)

	<u>Page</u>
TABLE 8-15. COUNT OF FACILITIES HAVING POSITIVE AND ZERO CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) UNDER THE THREE CONTROL OPTIONS, FOR AFFECTED INDUSTRY GROUPS	8-51
TABLE 8-16. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) PER CUBIC METER OF FACILITY CHAMBER VOLUME, FOR AFFECTED INDUSTRY GROUPS	8-53
TABLE 8-17. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) PER METRIC TON OF ETHYLENE OXIDE USED BY FACILITY, FOR AFFECTED INDUSTRY GROUPS	8-55
TABLE 8-18. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) AS A PERCENTAGE OF BASELINE ANNUAL STERILIZATION COSTS, FOR AFFECTED INDUSTRY GROUPS	8-57
TABLE 8-19. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) AS A PERCENTAGE OF ANNUAL FACILITY SALES, FOR AFFECTED INDUSTRY GROUPS	8-60
TABLE 8-20. SMALL BUSINESSES IN THE INDUSTRY GROUPS PERFORMING IN-HOUSE STERILIZATION	8-71
TABLE A-1. EVOLUTION OF THE BACKGROUND INFORMATION DOCUMENT	A-1
TABLE C-1. SUMMARY OF TEST RESULTS	C-2
TABLE C-2. SUMMARY OF FIELD TEST AT BURRON MEDICAL	C-5
TABLE C-3. SUMMARY OF EMISSION MEASUREMENTS AND CONTROL EFFICIENCIES FOR EMPTY CHAMBER TESTS AT BURRON MEDICAL	C-7
TABLE C-4. SUMMARY OF EMISSION MEASUREMENTS AND CONTROL EFFICIENCIES FOR TESTS AT THE MCCORMICK AND COMPANY, INC., SPICE MILL	C-12
TABLE C-5. SUMMARY OF EMISSION MEASUREMENTS AND CONTROL EFFICIENCIES FOR EMPTY CHAMBER TESTS AT CHESEBOROUGH PONDS	C-15
TABLE E-1. COST OF DAMAS SCRUBBER MODELS	E-3
TABLE E-2. CAPITAL AND ANNUALIZED COSTS OF INSTALLING SCRUBBERS	E-4

LIST OF TABLES (continued)

	<u>Page</u>
TABLE E-3. DATA USED TO CALCULATE SCRUBBER EQUIPMENT CAPITAL COSTS	E-5
TABLE E-4. CAPITAL COST OF CHECK VALVE FOR CHAMBER . . .	E-6
TABLE E-5. DATA USED TO CALCULATE CONTROL DEVICE ANNUALIZED COSTS	E-7
TABLE E-6. MISCELLANEOUS OPERATING COSTS	E-8
TABLE E-7. COST OF ETO ABATOR TM CATALYTIC OXIDERS	E-9
TABLE E-8. AERATION ROOM GAS/SOLID REACTANT CONTROL COST ANALYSIS	E-18
TABLE E-9. AERATION ROOM CATALYTIC OXIDATION CONTROL COST ANALYSIS	E-24
TABLE E-10. CAPITAL AND ANNUAL COSTS OF INSTALLING SCRUBBERS	E-32
TABLE E-11. CAPITAL AND ANNUAL COSTS OF INSTALLING SCRUBBERS TO CONTROL CHAMBER EXHAUST VENTS . .	E-34
TABLE E-12. CAPITAL AND ANNUAL COSTS OF GAS/SOLID REACTOR TO CONTROL AERATION UNITS AT AN EXAMPLE FACILITY	E-36
TABLE E-13. CAPITAL AND ANNUALIZED COSTS OF CATALYTIC OXIDATION AT AN EXAMPLE FACILITY	E-38
TABLE E-14. INCREMENTAL CAPITAL COSTS OF MANIFOLDING STERILIZATION CHAMBERS	E-42
TABLE E-15. DUCTWORK COSTS OF MANIFOLDING CHAMBER EXHAUST VENTS TO A SCRUBBER	E-44
TABLE E-16. DUCTWORK COSTS OF MANIFOLDING AERATION UNITS TO A GAS/SOLID REACTOR	E-45
TABLE E-17. CHEMICAL ENGINEERING COST INDICES	E-48

1.0 SUMMARY

1.1 STATUTORY AUTHORITY

National emission standards for hazardous air pollutants are established in accordance with Section 112(b)(1)(B) of the Clean Air Act (42 U.S.C. 7412), as amended. Emission standards under Section 112 apply to new and existing sources of a substance that has been listed as a hazardous air pollutant. This study examines emissions of ethylene oxide (EO) from commercial sterilization and fumigation industries.

1.2 REGULATORY ALTERNATIVES

Five regulatory alternatives representing selected combinations of control options were developed to evaluate the environmental and cost impacts of differing control strategies.

Regulatory Alternative A represents the maximum level of control with 99 percent of the EO emissions from all emissions points associated with commercial sterilization operations captured and controlled. Regulatory Alternative B represents the maximum level of control of all emissions points that exceed an EO use cutoff. Regulatory Alternative C represents control of the sterilizer vent, vacuum pump drain, and aeration room emissions at this same level of EO use. Additional controls on chamber exhaust emissions are not anticipated under this alternative. Regulatory Alternative D represents control of only the sterilizer vent and vacuum pump drain emissions for facilities using 270 kilograms per year (kg/yr) (600 pounds per year [lb/yr]) or more of EO. Regulatory Alternative E represents control of these same two emissions points for facilities using 900 kg/yr (2,000 lb/yr) or more of EO. Regulatory Alternative E

represents the maximum achievable control technology (MACT) floor determination.

1.3 ENVIRONMENTAL IMPACT

Table 1-1 summarizes the environmental impacts of the regulatory alternatives. At the MACT floor (Regulatory Alternative E), the nationwide EO emissions are estimated at 120 megagrams per year (Mg/yr) (132 tons per year [tons/yr]). The lower EO use cutoff proposed under Regulatory Alternative D reduces the estimated nationwide EO emissions to 109 Mg/yr (120 tons/yr). The control options under Regulatory Alternative C reduce the nationwide emissions to 68 Mg/yr (75 tons/yr). Under Regulatory Alternatives B and A, the control options proposed would reduce the nationwide emissions of EO to 30 Mg/yr and 11 Mg/yr (33 tons/yr and 12 tons/yr), respectively.

The potential impacts of these regulatory alternatives on wastewater, solid waste, and energy are also shown in Table 1-1. It is expected that the wastewater and solid waste impacts will be insignificant because of the recycling of ethylene glycol and reactant.

1.4 COST IMPACT

The nationwide cost impacts of the regulatory alternatives are summarized in Table 1-2. The costs associated with Regulatory Alternative E (MACT floor regulation) may require a nationwide capital investment of about \$3.8 million. The control measures in Regulatory Alternatives D, C, B, and A may each require a nationwide capital investment of about \$4.3 million, \$6.4 million, \$9.2 million, and \$12 million respectively. These cost figures were determined using fourth quarter 1987 dollars.

1.5 ECONOMIC IMPACT

The economic impacts associated with the regulation of commercial sterilizers are not significant. In general, sterilization costs represent a small fraction of total production costs for facilities in industries in which sterilization is not the main source of revenue. Thus, any cost increases caused by the regulation will not significantly increase total production costs. Furthermore, because total

TABLE 1-1. POTENTIAL NATIONWIDE PERCENT EMISSIONS REDUCTION AND NATIONWIDE AIR, WASTEWATER, SOLID WASTE, AND ENERGY IMPACTS

Regulatory Alternative	Nationwide emission reduction, %	EO air emission reduction Mg/yr (tons/yr)	Total annual wastewater production, m ³ (gal) ^{a, b}	Total annual solid waste production, Mg/(tons) ^{c, d}	Total annual electricity consumption, Kw/h (000's)
A	99	1,061 (1,170)	2,150 (569,000)	190 (209)	4,600
B	97	1,042 (1,148)	2,140 (566,000)	137 (151)	2,700
C	94	1,004 (1,107)	2,140 (566,000)	137 (151)	2,700
D	90	963 (1,062)	2,140 (566,000)	0	0
E	89	952 (1,049)	2,120 (561,000)	0	0

^aActual impacts anticipated to be zero because of recycling of ethylene glycol.

^bApproximately 60 percent (by volume) of wastewater is composed of ethylene glycol.

^cActual impacts anticipated to be zero because of recycling of reactant.

^dBased on the use of gas/solid reactor.

Source: U. S. EPA Ethylene Oxide Commercial Sterilization Data Base, 1986, 1988.

TABLE 1-2. NATIONWIDE REGULATORY ALTERNATIVE COST IMPACTS

Regulatory Alternative	Emission reduction, %	Total annual costs, \$/MM	Emission reduction, Mg/yr (tons/yr)	Cost effectiveness \$/Mg (\$/ton)	Incremental cost effectiveness, \$/Mg (\$/ton)
A	99	12	1,061 (1,170)	11,300 (10,300)	147,000 (133,000)
B	97	9.2	1,042 (1,149)	8,800 (8,000)	74,000 (67,000)
C	94	6.4	1,004 (1,107)	6,400 (5,800)	51,000 (46,000)
D	90	4.3	963 (1,062)	4,500 (4,050)	45,000 (41,000)
E	89	3.8	952 (1,049)	4,000 (3,600)	N/A

^aEthylene oxide use cutoff same as for sterilizer vent.

^bStatus quo means that baseline chambers exhaust emissions are not exceeded.

production costs will not increase substantially, the price increases required to recover control also will be low.

In the contract sterilization industry, sterilization is nearly the entire product, and thus is the main source of revenue. Therefore, increased sterilization costs due to the regulation may cause total production costs and prices to increase significantly. However, as a result of the regulation, these facilities should experience an increase in demand for their services through facilities switching from in-house sterilization to contract sterilization. This increase in demand should allow them to recover control costs and may even increase profits for facilities in the contract sterilization industry. Thus, contract sterilizers are not adversely impacted by the regulation of commercial sterilizers.

2.0 INTRODUCTION

2.1 BACKGROUND AND AUTHORITY FOR STANDARDS

According to industry estimates, more than 2.4 billion pounds of toxic pollutants were emitted to the atmosphere in 1988 ("Implementation Strategy for the Clean Air Act Amendments of 1990," Environmental Protection Agency [EPA] Office of Air and Radiation, January 15, 1991). These emissions may result in a variety of adverse health effects, including cancer, reproductive effects, birth defects, and respiratory illnesses. Title III of the 1990 Amendments to the Clean Air Act provides the tools for controlling emissions of these pollutants. Emissions from both large and small facilities that contribute to air toxics problems in urban and other areas will be regulated. The primary consideration in establishing national industry standards must be demonstrated technology. Before national emission standards for hazardous air pollutants (NESHAP) are proposed as Federal regulations, air pollution prevention and control methods are examined in detail with respect to their feasibility, environmental impacts, and costs. Various control options based on different technologies and degrees of efficiency are examined, and a determination is made regarding whether the various control options apply to each emissions source or if dissimilarities exist between the sources. In most cases, regulatory alternatives are subsequently developed and are then studied by EPA as a prospective basis for a standard. The alternatives are investigated in terms of their impacts on the environment, the economics and well-being of the industry, the national economy, and energy and other impacts. This document summarizes the information obtained through these studies so that interested

persons will be able to evaluate the information considered by EPA in developing the proposed standards.

National emission standards for hazardous air pollutants for new and existing sources are established under Section 112 of the Clean Air Act as amended in 1990 [42 U.S.C. 7401 et seq., as amended by PL 101-549, November 15, 1990], hereafter referred to as the Act. Section 112 directs the EPA Administrator to promulgate standards that "require the maximum degree of reduction in emissions of the hazardous air pollutants subject to this section (including a prohibition of such emissions, where achievable) that the Administrator, taking into consideration the cost of achieving such emission reductions, and any non-air quality health and environmental impacts and energy requirements, determines is achievable" The Act allows the Administrator to set standards that "distinguish among classes, types, and sizes of sources within a category or subcategory."

The Act differentiates between major sources and area sources. A major source is defined as "any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants." The Administrator, however, may establish a lesser quantity cutoff to distinguish between major and area sources. The level of the cutoff is based on the potency, persistence, or other characteristics or factors of the air pollutant. An area source is defined as "any stationary source of hazardous air pollutants that is not a major source." For new sources, the 1990 Amendments state that the "maximum degree of reduction in emissions that is deemed achievable for new sources in a category or subcategory shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source, as determined by the Administrator." Emission standards for existing sources "may be less stringent than the standards for new sources in the same

category or subcategory but shall not be less stringent, and may be more stringent than--

(A) the average emission limitation achieved by the best performing 12 percent of the existing sources (for which the Administrator has emissions information), excluding those sources that have, within 18 months before the emission standard is proposed or within 30 months before such standard is promulgated, whichever is later, first achieved a level of emission rate or emission reduction which complies, or would comply if the source is not subject to such standard, with the lowest achievable emission rate (as defined by Section 171) applicable to the source category and prevailing at the time, in the category or subcategory for categories and subcategories with 30 or more sources, or

(B) the average emission limitation achieved by the best performing five sources (for which the Administrator has or could reasonably obtain emissions information) in the category or subcategory for categories or subcategories with fewer than 30 sources."

The Federal standards are also known as "MACT" standards and are based on the maximum achievable control technology previously discussed. The MACT standards may apply to both major and area sources, although the existing source standards may be less stringent than the new source standards, within the constraints presented above. The MACT is considered to be the basis for the standard, but the Administrator may promulgate more stringent standards that have several advantages. First, they may help achieve long-term cost savings by avoiding the need for more expensive retrofitting to meet possible future residual risk standards, which may be more stringent (discussed in Section 2.6). Second, Congress was clearly interested in providing incentives for improving technology. Finally, in the 1990 Amendments, Congress gave EPA a clear mandate to reduce the health and environmental risk of air toxics emissions as quickly as possible.

For area sources, the Administrator may "elect to promulgate standards or requirements applicable to sources in such categories or subcategories which provide for the use of generally available control technologies or management practices by such sources to reduce emissions of hazardous air pollutants." These area source standards are also known as "GACT" (generally available control technology) standards, although MACT may be applied at the Administrator's discretion, as discussed previously.

The standards for hazardous air pollutants (HAP's), like the new source performance standards (NSPS) for criteria pollutants required by Section 111 of the Act (42 U.S.C. 7411), differ from other regulatory programs required by the Act (such as the new source review program and the prevention of significant deterioration program) in that NESHAP and NSPS are national in scope (versus site-specific). Congress intended for the NESHAP and NSPS programs to provide a degree of uniformity to State regulations to avoid situations where some States may attract industries by relaxing standards relative to other States. States are free under Section 116 of the Act to establish standards more stringent than Section 111 or 112 standards.

Although NESHAP are normally structured in terms of numerical emissions limits, alternative approaches are sometimes necessary. In some cases, physically measuring emissions from a source may be impossible or at least impracticable due to technological and economic limitations. Section 112(h) of the Act allows the Administrator to promulgate a design, equipment, work practice, or operational standard, or combination thereof, in those cases where it is not feasible to prescribe or enforce an emissions standard. For example, emissions of volatile organic compounds (many of which may be HAP's, such as benzene) from storage vessels for volatile organic liquids are greatest during tank filling. The nature of the emissions (i.e, high concentrations for short periods during filling and low concentrations for longer periods during storage) and the configuration of storage tanks make direct emission measurement

impractical. Therefore, the MACT or GACT standards may be based on equipment specifications.

Under Section 112(h)(3), the Act also allows the use of alternative equivalent technological systems: "If, after notice and opportunity for comment, the owner or operator of any source establishes to the satisfaction of the Administrator that an alternative means of emission limitation" will reduce emissions of any air pollutant at least as much as would be achieved under the design, equipment, work practice, or operational standard, the Administrator shall permit the use of the alternative means.

Efforts to achieve early environmental benefits are encouraged in Title III. For example, source owners and operators are encouraged to use the Section 112(i)(5) provisions, which allow a 6-year compliance extension of the MACT standard in exchange for the implementation of an early emission reduction program. The owner or operator of an existing source must demonstrate a 90-percent emission reduction of HAP's (or 95 percent if the HAP's are particulates) and meet an alternative emission limitation, established by permit, in lieu of the otherwise applicable MACT standard. This alternative limitation must reflect the 90- (95-) percent reduction and is in effect for a period of 6 years from the compliance date for the otherwise applicable standard. The 90- (95-) percent early emission reduction must be achieved before the otherwise applicable standard is first proposed, although the reduction may be achieved after the standard's proposal (but before January 1, 1994) if the source owner or operator makes an enforceable commitment before the proposal of the standard to achieve the reduction. The source must meet several criteria to qualify for the early reduction standard, and Section 112(i)(5)(A) provides that the State may require additional reductions.

2.2 SELECTION OF POLLUTANTS AND SOURCE CATEGORIES

As amended in 1990, the Act includes a list of 189 HAP's. Petitions to add or delete pollutants from this list may be submitted to EPA. Using this list of pollutants, EPA will publish a list of source categories (major and area sources) for

which emission standards will be developed. Within 2 years of enactment (November 1992), EPA will publish a schedule establishing dates for promulgating these standards. Petitions also may be submitted to EPA to remove source categories from the list. The schedule for standards for source categories will be determined according to the following criteria:

- "(A) the known or anticipated adverse effects of such pollutants on public health and the environment;
- (B) the quantity and location of emissions or reasonably anticipated emissions of hazardous air pollutants that each category or subcategory will emit; and
- (C) the efficiency of grouping categories or subcategories according to the pollutants emitted, or the processes or technologies used."

After the source category has been chosen, the types of facilities within the source category to which the standard will apply must be determined. A source category may have several facilities that cause air pollution, and emissions from these facilities may vary in magnitude and control cost. Economic studies of the source category and applicable control technology may show that air pollution control is better served by applying standards to the more severe pollution sources. For this reason, and because there is no adequately demonstrated system for controlling emissions from certain facilities, standards often do not apply to all facilities at a source. For the same reasons, the standards may not apply to all air pollutants emitted. Thus, although a source category may be selected to be covered by standards, the standards may not cover all pollutants or facilities within that source category.

2.3 PROCEDURE FOR DEVELOPMENT OF NESHAP

Standards for major and area sources must (1) realistically reflect MACT or GACT; (2) adequately consider the cost, the non-air quality health and environmental impacts, and the energy requirements of such control; (3) apply to new and existing sources; and (4) meet these conditions for all variations of industry operating conditions anywhere in the country.

The objective of the NESHAP program is to develop standards to protect the public health by requiring facilities to control emissions to the level achievable according to the MACT or GACT guidelines. The standard-setting process involves three principal phases of activity: (1) gathering information, (2) analyzing the information, and (3) developing the standards.

During the information-gathering phase, industries are questioned through telephone surveys, letters of inquiry, and plant visits by EPA representatives. Information is also gathered from other sources, such as a literature search. Based on the information acquired about the industry, EPA selects certain plants at which emissions tests are conducted to provide reliable data that characterize the HAP emissions from well-controlled existing facilities.

In the second phase of a project, the information about the industry, the pollutants emitted, and the control options are used in analytical studies. Hypothetical "model plants" are defined to provide a common basis for analysis. The model plant definitions, national pollutant emissions data, and existing State regulations governing emissions from the source category are then used to establish "regulatory alternatives." These regulatory alternatives may be different levels of emissions control or different degrees of applicability or both.

The EPA conducts studies to determine the cost, economic, environmental, and energy impacts of each regulatory alternative. From several alternatives, EPA selects the single most plausible regulatory alternative as the basis for the NESHAP for the source category under study.

In the third phase of a project, the selected regulatory alternative is translated into standards, which, in turn, are written in the form of a Federal regulation. The Federal regulation limits emissions to the levels indicated in the selected regulatory alternative.

As early as is practical in each standard-setting project, EPA representatives discuss the possibilities of a standard and the form it might take with members of the National Air Pollution

Control Techniques Advisory Committee, which is composed of representatives from industry, environmental groups, and State and local air pollution control agencies. Other interested parties also participate in these meetings.

The information acquired in the project is summarized in the background information document (BID). The BID, the proposed standards, and a preamble explaining the standards are widely circulated to the industry being considered for control, environmental groups, other government agencies, and offices within EPA. Through this extensive review process, the points of view of expert reviewers are taken into consideration as changes are made to the documentation.

A "proposal package" is assembled and sent through the offices of EPA Assistant Administrators for concurrence before the proposed standards are officially endorsed by the EPA Administrator. After being approved by the EPA Administrator, the preamble and the proposed regulation are published in the Federal Register.

The public is invited to participate in the standard-setting process as part of the Federal Register announcement of the proposed regulation. The EPA invites written comments on the proposal and also holds a public hearing to discuss the proposed standards with interested parties. All public comments are summarized and incorporated into a second volume of the BID. All information reviewed and generated in studies in support of the standards is available to the public in a "docket" on file in Washington, D.C. Comments from the public are evaluated, and the standards may be altered in response to the comments.

The significant comments and EPA's position on the issues raised are included in the preamble of a promulgation package, which also contains the draft of the final regulation. The regulation is then subjected to another round of internal EPA review and refinement until it is approved by the EPA Administrator. After the Administrator signs the regulation, it is published as a "final rule" in the Federal Register.

2.4 CONSIDERATION OF COSTS

The requirements and guidelines for the economic analysis of proposed NESHAP are prescribed by Presidential Executive Order 12291 (EO 12291) and the Regulatory Flexibility Act (RFA). The EO 12291 requires preparation of a Regulatory Impact Analysis (RIA) for all "major" economic impacts. An economic impact is considered to be major if it satisfies any of the following criteria:

1. An annual effect on the economy of \$100 million or more;
2. A major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions; or
3. Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

An RIA describes the potential benefits and costs of the proposed regulation and explores alternative regulatory and nonregulatory approaches to achieving the desired objectives. If the analysis identifies less costly alternatives, the RIA includes an explanation of the legal reasons why the less costly alternatives could not be adopted. In addition to requiring an analysis of the potential costs and benefits, EO 12291 specifies that EPA, to the extent allowed by the Act and court orders, demonstrate that the benefits of the proposed standards outweigh the costs and that the net benefits are maximized.

The RFA requires Federal agencies to give special consideration to the impact of regulations on small businesses, small organizations, and small governmental units. If the proposed regulation is expected to have a significant impact on a substantial number of small entities, a regulatory flexibility analysis must be prepared. In preparing this analysis, EPA takes into consideration such factors as the availability of capital for small entities, possible closures among small entities, the increase in production costs due to compliance, and a comparison

of the relative compliance costs as a percent of sales for small versus large entities.

The prime objective of the cost analysis is to identify the incremental economic impacts associated with compliance with the standards based on each regulatory alternative compared to baseline. Other environmental regulatory costs may be factored into the analysis wherever appropriate. Air pollutant emissions may cause water pollution problems, and captured potential air pollutants may pose a solid waste disposal problem. The total environmental impact of an emission source must, therefore, be analyzed and the costs determined whenever possible.

A thorough study of the profitability and price-setting mechanisms of the industry is essential to the analysis so that an accurate estimate of potential adverse economic impacts can be made for proposed standards. It is also essential to know the capital requirements for pollution control systems already placed on plants so that the additional capital requirements necessitated by these Federal standards can be placed in proper perspective. Finally, it is necessary to assess the availability of capital to provide the additional control equipment needed to meet the standards.

2.5 CONSIDERATION OF ENVIRONMENTAL IMPACTS

Section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969 requires Federal agencies to prepare detailed environmental impact statements on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment. The objective of NEPA is to build into the decision-making process of Federal agencies a careful consideration of all environmental aspects of proposed actions.

In a number of legal challenges to standards for various industries, the United States Court of Appeals for the District of Columbia Circuit has held that environmental impact statements need not be prepared by EPA for proposed actions under the Act. Essentially, the Court of Appeals has determined that the best system of emissions reduction requires the Administrator to take into account counterproductive environmental effects of proposed

standards as well as economic costs to the industry. On this basis, therefore, the Courts established a narrow exemption from NEPA for EPA determinations.

In addition to these judicial determinations, the Energy Supply and Environmental Coordination Act (ESECA) of 1974 (PL-93-319) specifically exempted proposed actions under the Act from NEPA requirements. According to Section 7(c)(1), "No action taken under the Clean Air Act shall be deemed a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969" (15 U.S.C. 793(c)(1)).

Nevertheless, EPA has concluded that preparing environmental impact statements could have beneficial effects on certain regulatory actions. Consequently, although not legally required to do so by Section 102(2)(C) of NEPA, EPA has adopted a policy requiring that environmental impact statements be prepared for various regulatory actions, including NESHAP developed under Section 112 of the Act. This voluntary preparation of environmental impact statements, however, in no way legally subjects the EPA to NEPA requirements.

To implement this policy, a separate section is included in this document that is devoted solely to an analysis of the potential environmental impacts associated with the proposed standards. Both adverse and beneficial impacts in such areas as air and water pollution, increased solid waste disposal, and increased energy consumption are discussed.

2.6 RESIDUAL RISK STANDARDS

Section 112 of the Act provides that 8 years after MACT standards are established (except for those standards established 2 years after enactment, which have 9 years), standards to protect against the residual health and environmental risks remaining must be promulgated, if necessary. The standards would be triggered if more than one source in a category or subcategory exceeds a maximum individual risk of cancer of 1 in 1 million. These residual risk regulations would be based on the concept of providing an "ample margin of safety to protect public health."

The Administrator may also consider whether a more stringent standard is necessary to prevent--considering costs, energy, safety, and other relevant factors--an adverse environmental effect. In the case of area sources controlled under GACT standards, the Administrator is not required to conduct a residual risk review.

3.0 ETHYLENE OXIDE STERILIZATION/FUMIGATION PROCESSES AND EMISSIONS

3.1 BACKGROUND INFORMATION

The commercial sterilization (CS) source category covers the use of ethylene oxide (EO) as a sterilant/fumigant in the production of medical equipment supplies and in miscellaneous sterilization and fumigation operations. Commercial sterilization facilities use EO as a sterilant for heat- or moisture-sensitive materials or as a fumigant to control microorganisms or insects. A variety of materials are sterilized or fumigated with EO, including medical equipment (e.g., syringes and surgical gloves), spices, cosmetics, and pharmaceuticals. These materials may be sterilized at the facility that produces or uses the product or by contract sterilizers (i.e., firms under contract to sterilize products manufactured by other companies). Libraries and museums use EO to fumigate books and other historical items. State departments of agriculture control diseases of bees by fumigating beehives with EO.

Information about facilities that use EO as a sterilant/fumigant was obtained from two sources: (1) a survey of medical equipment suppliers (Health Industry Manufacturers' Association [HIMA] members) conducted by HIMA in November 1985 and (2) an information collection request (ICR) submitted by EPA under Section 114 of the Act to miscellaneous sterilizers and fumigators (identified during an extensive survey of potential users) in July 1986. A total of 203 CS facilities responded to the HIMA survey and the July 1986 EPA information request to complete the 1986 data base.^{1,2}

Additional information to the 1986 data base was obtained from two Section 114 letters (July 1988 and July 1989). The July 1988 Section 114 letter was sent to 44 (9 parent companies) of the 203 facilities represented in the 1986 data base.³ These 44 facilities were chosen because they represent the diversity of sterilizer chamber sizes, annual EO use, and industries associated with the commercial sterilization category. Although these facilities represent only 22 percent of the number of facilities in the CS data base, the emissions from these facilities account for 64 percent of the total emissions from commercial sterilization facilities. The July 1988 Section 114 letter was used to obtain detailed operating parameters for a short-term health risk assessment analysis; data on vacuum pumps, gas types, control devices, and aeration rooms were also obtained from this ICR. The July 1989 Section 114 letter was sent to 39 of the 203 facilities in the 1986 data base (i.e., those with a maximum individual risk [MIR] of cancer incidence greater than 10^{-3}).⁴ The purpose of this Section 114 letter was to update EPA's Air Toxics Exposure and Risk Information System (ATERIS) data base. The July 1989 Section 114 letter was also used to obtain updated information regarding EO use, emission controls, and vacuum pumps. The responses to the July 1989 Section 114 letter indicated that 7 of the 39 facilities had ceased EO use. Therefore, 196 facilities comprise the EPA 1989 CS data base.

As shown in Table 3-1, the facilities represented in the EPA commercial sterilization data base are located in 41 States and Puerto Rico. These facilities were grouped by Standard Industrial Classification (SIC) into the following categories:

1. medical equipment suppliers;
2. pharmaceuticals;
3. other health-related industries;
4. spice manufacturers;
5. contract sterilizers;
6. libraries, museums, and archives;

TABLE 3-1. LOCATIONS OF FACILITIES--EPA COMMERCIAL
STERILIZATION DATA BASE¹⁻⁴

State	No. of facilities	State	No. of facilities
Arizona	3	Missouri	5
Arkansas	2	New Hampshire	2
California	19	New Jersey	17
Colorado	3	New York	13
Connecticut	6	North Carolina	7
Delaware	2		
Florida	5	Ohio	2
Georgia	4	Pennsylvania	9
Illinois	8	Puerto Rico	14
Indiana	4	Rhode Island	2
Iowa	3	South Carolina	2
Maryland	5	Tennessee	3
Massachusetts	9	Texas	12
Michigan	8	Utah	1
Minnesota	6	Virginia	5
Mississippi	<u>2</u>	Washington	<u>2</u>
Subtotal	89	Subtotal	96
<p>The commercial sterilization data base includes one facility located in each of the following States: Alabama, Hawaii, Kentucky, Maine, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Wisconsin, and West Virginia.</p>			
Subtotal	11		
Total No. of facilities	196		

7. laboratories (research, testing, and animal breeding);
and

8. State departments of agriculture.⁵

Table 3-2 shows the number of facilities in the EPA commercial sterilization data base for the eight categories listed above and the SIC codes represented by these industry categories.

3.2 PROCESS DESCRIPTION

There are two main types of EO sterilization processes:

(1) bulk sterilization and (2) single-item sterilization. These processes are described below followed by discussions about spice fumigators, library and museum fumigators, and beehive fumigators used by State departments of agriculture. (In addition to using the bulk sterilization process, one facility also sterilizes within 55-gallon drums.² This process, which is neither bulk nor single-item sterilization, is not discussed.)

3.2.1 Bulk Sterilization

Bulk sterilization is the more commonly used EO sterilization process; 98 percent of the commercial sterilization facilities represented in the EPA data base use this process.¹⁻⁴ The products to be sterilized are placed in a sterilization chamber and are exposed to a sterilant gas at a predetermined temperature, humidity level, and pressure. The equipment, sterilant gases, and sterilization cycle used for bulk sterilization processes are described below.

3.2.1.1 Equipment. A schematic of a gas sterilizer is shown in Figure 3-1. The main components of the sterilizer are the chamber and vacuum pump. Chambers used by commercial sterilization facilities typically range in volume from 2.8 cubic meters (m^3) (100 cubic feet [ft^3]) to 28 m^3 (1,000 ft^3).^{1,2} Table 3-3 presents size data for the chambers in the EPA commercial sterilization data base.

A vacuum pump is used to remove air from the chamber before sterilization begins and to evacuate the sterilant gas after the sterilization cycle is complete. In the past, once-through, water-ring vacuum pumps were used. However, many facilities are converting to full sealant recovery (i.e., oil-sealed or

TABLE 3-2. NUMBER OF FACILITIES AND STANDARD INDUSTRIAL
CLASSIFICATION (SIC) PER INDUSTRY CATEGORY--
EPA COMMERCIAL STERILIZATION DATA BASE⁵

Industry category	No. of facilities	SIC
Medical equipment suppliers	61	3841, 3842
Pharmaceuticals	39	2834, 5122, 2831, 2833
Other health-related industries	24	3079, 3693, 5086, 2211, 2821, 2879, 3069, 3569, 3677, 3999
Spice manufacturers	23	2099, 5149, 2034, 2035, 2046
Contract sterilizers	17	7399, 7218, 8091
Libraries, museums, and archives	13	8411, 8231
Laboratories (research, testing and animal breeding)	11	0279, 7391, 8071, 8922, 7397
State departments of agriculture	8	9641
Total	196	

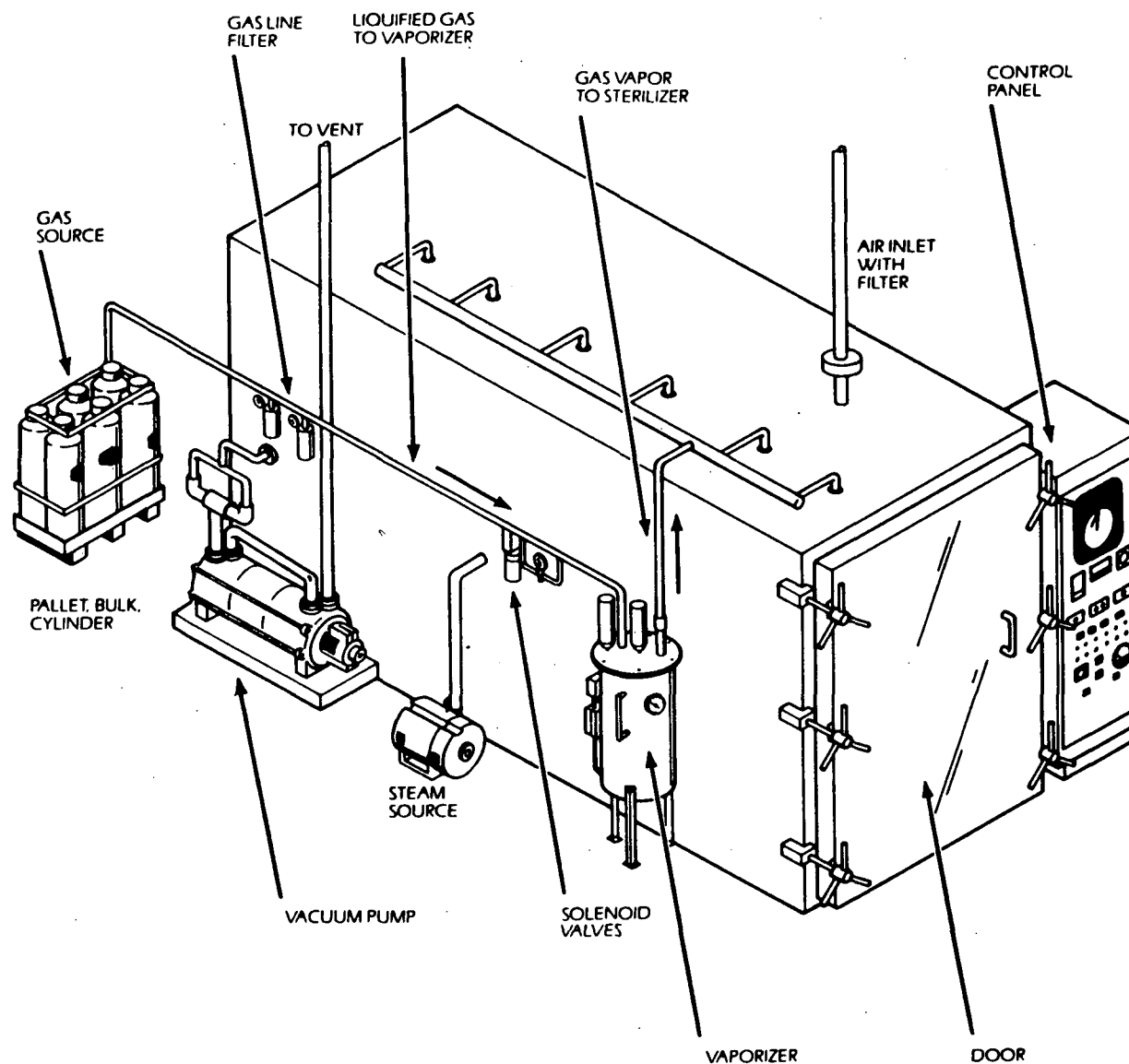


Figure 3-1. Schematic of a gas sterilizer.
(Courtesy of Union Carbide Corporation, Linde Division.)⁷

TABLE 3-3. CHAMBER SIZES--EPA COMMERCIAL
STERILIZATION DATA BASE^{1,2}

Size range, m ³ (ft ³)	No. of chambers	Percent	Cumulative No. of chambers	Cumulative percent
≤1.4 (≤50)	83	20	83	20
1.5-2.8 (51-100)	29	7	112	28
2.9-14 (101-500)	113	28	225	55
15-28 (501-1,000)	116	29	341	84
29-57 (1,001-2,000)	55	14	396	98
≥58 (≥2,001)	11	2	407 ^a	100
^a This number excludes four single-item sterilization units, one 55-gal drum user, and two facilities that did not report a chamber size.				

recirculating water) vacuum pumps in order to meet the 1 part per million by volume (1 ppmv) Occupational Safety and Health Administration (OSHA) worker exposure standard for EO and proposed State regulations.^{3,6}

3.2.1.2 Sterilant Gases. Ethylene oxide is an extremely effective sterilant gas. The EO penetrates product packaging (e.g., cardboard shipping box, plastic shrink wrap, paper box, and product wrapping) and destroys bacteria and viruses on the product. The product remains sterile until use because bacteria and viruses cannot penetrate the product wrapping.

The most widely used sterilant gas is a mixture of 12 percent by weight EO and 88 percent by weight dichlorodifluoromethane (CFC-12), referred to as 12/88. Two other commonly used sterilant gases are (1) pure EO (i.e., 100 percent EO) and (2) a mixture of 10 percent by weight EO and 90 percent by weight carbon dioxide (CO₂), referred to as 10/90. Other sterilant gas mixtures that are used include 20/80, 30/70, and 80/20 (weight percents EO/CO₂).^{1,2,4} Gas mixtures that contain 20 percent or greater EO (by weight) are considered flammable. The 80/20 (EO/CO₂) mixture has the same flammability range as pure EO.⁷ Physical and chemical properties of EO, CFC-12, and CO₂ are given in Table 3-4. Table 3-5 shows the number of commercial sterilization facilities represented in the EPA data base that use a particular gas type and the amount of EO used for each gas type. Since many commercial sterilization facilities operate more than one sterilization chamber, the gas usage rates in Table 3-5 also are presented on a chamber basis.^{1,2,4} The data presented in Table 3-5 are based on information from the 1985 HIMA survey and the 1986 EPA ICR.^{1,2} Gas type data were collected for the 44 facilities that responded to the 1988 Section 114 letter; however, this information was not updated for the remaining facilities represented in the 1989 CS data base. Since 1986, the increased price of CFC-12 (due to EPA regulation of CFC production) could have affected the number of facilities that use 12/88.

TABLE 3-4. PHYSICAL AND CHEMICAL PROPERTIES OF ETHYLENE OXIDE,
DICHLORODIFLUOROMETHANE, AND CARBON DIOXIDE ⁸⁻¹¹

	Ethylene oxide	Dichlorodifluoromethane	Carbon dioxide
Other designations	1,2-epoxyethane, oxirane, dimethylene oxide	CFC-12, refrigerant 12, propellant 12	Carbonic acid gas, carbonic anhydride
Appearance	Colorless liquid or gas	Colorless gas, readily liquified under pressure and/or cooling	Colorless gas
Chemical formula	C ₂ H ₄ O	CCl ₂ F ₂	CO ₂
Molecular weight	44.0	120.9	44.0
Vapor pressure at 20°C (68°F)	146.0 kPa (21.2 psia)	567.6 kPa (82.3 psia)	5,731.0 kPa (831 psia)
Boiling point at 101.3 kPa (14.7 psi)	10.4°C (50.7°F)	-29.8°C (-21.6°F)	-78.5°C (-109.3°F)
Flammability limits in air	Lower 3 percent by volume Upper 80+ percent by volume ^a	Nonflammable	Nonflammable
Water solubility	Completely miscible	Low solubility	--
Heat of combustion, vapor at 25°C (77°F)	1,306 kJ/mol (12,760 Btu/lb)	111 kJ/mol (396 Btu/lb)	--
Threshold limit value (TLV) 8-hr time weighted average (TWA)	1 ppmv	1,000 ppmv	5,000 ppmv

^aPure EO explodes by decomposition at 560°C (1040°F) with ignition.

TABLE 3-5. STERILANT GAS TYPE USAGE--EPA COMMERCIAL STERILIZATION DATA BASE 1-4

Sterilant gas	No. of facilities ^a	Percent of facilities	No. of chambers ^b	Percent of chambers	EO use, Mg/yr ^c	Percent of total EO use
12/88 (EO/CFC-12)	151	77	282	64	639	33
Pure EO	40	20	113	26	1,027	54
10/90 (EO/CO ₂)	14	7	19	4	4	<0.01
Other mixtures ^d	16	8	25	6	249	13

^aThere are 196 commercial sterilization facilities in the EPA data base. Approximately 10 percent of these facilities use more than one type of sterilant gas.

^bThere are 434 operational sterilization "chambers" (the four single-item sterilization systems are counted as chambers) in the EPA commercial sterilization data base. More than one type of sterilant gas is used in 5 percent of these chambers.

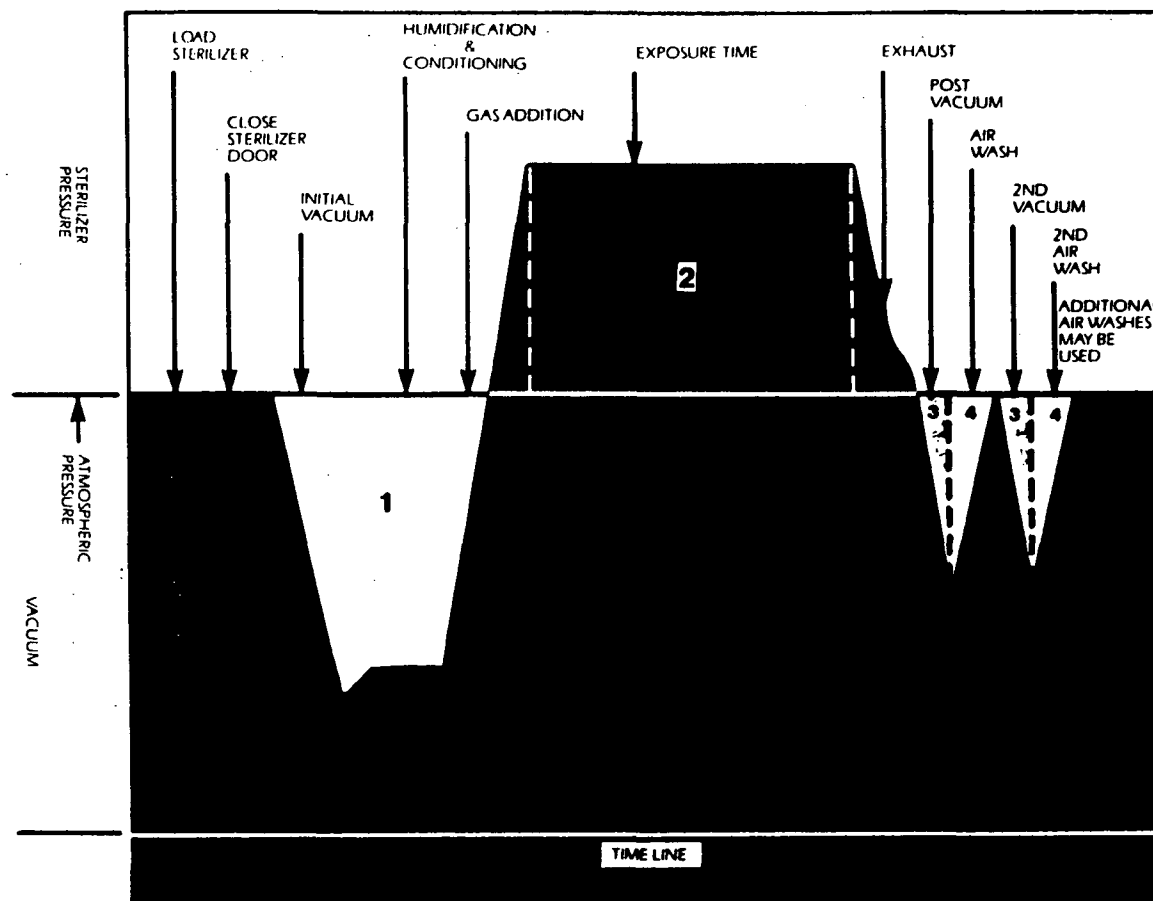
^cAmount of EO in the sterilant gas mixture.

^dIncludes mixture of EO and CO₂ with a weight percent of EO ranging from 20 to 80 percent and custom mixes.

The 12/88 mixture is popular for several reasons. Unlike pure EO, 12/88 is nonflammable and nonexplosive. Therefore, the use of 12/88 does not require explosion-proof rooms and additional safety precautions that are necessary when pure EO is used. The 10/90 mixture also is nonflammable and nonexplosive.⁷ But, because 10/90 is only 10 percent EO by volume whereas 12/88 is 27.3 percent EO by volume, 10/90 requires higher operating pressures to obtain an EO concentration that is sufficient for effective sterilization (approximately 304 kilopascals [kPa], or 44 pounds per square inch absolute [psia], for 10/90, as compared to 170 kPa [24.7 psia] for 12/88).¹² The chambers used for 10/90 sterilization must be ASME-rated pressure vessels, (i.e., manufactured in accordance with Section VIII, Division I, of the American Society of Mechanical Engineers [ASME] Pressure Vessel Code) and are, therefore, more expensive to construct than the chambers used with 12/88. However, because of insurance requirements, many commercial sterilization facilities use chambers that meet requirements for ASME-rated pressure vessels when sterilizing with 12/88 or with explosive mixtures below ambient pressure.¹³

3.2.1.3 Sterilization Cycle. The typical sterilization cycle consists of five phases: (1) presterilization conditioning, (2) sterilization, (3) evacuation, (4) air wash, (5) chamber exhaust, and (6) aeration. Figures 3-2 and 3-3 show pressure/time curves for the first four phases of the 12/88 sterilization cycle and the pure EO sterilization cycle, respectively. Steps 1 through 4 typically require about 8 hours.

3.2.1.3.1 Presterilization conditioning. After the products have been loaded into the chamber and the airtight door sealed, a partial vacuum is drawn inside the chamber. This initial vacuum, or drawdown, prevents dilution of the sterilant gas. Also, if flammable sterilant gases are used, the removal of air reduces the potential for ignition.⁷ The chamber pressure is reduced to a pressure of about 6.9 to 69 kPa (1 to 10 psia) for 12/88 and 3 kPa (0.4 psia) for pure EO. The initial drawdown takes from about 5 to 45 minutes, depending on the product being

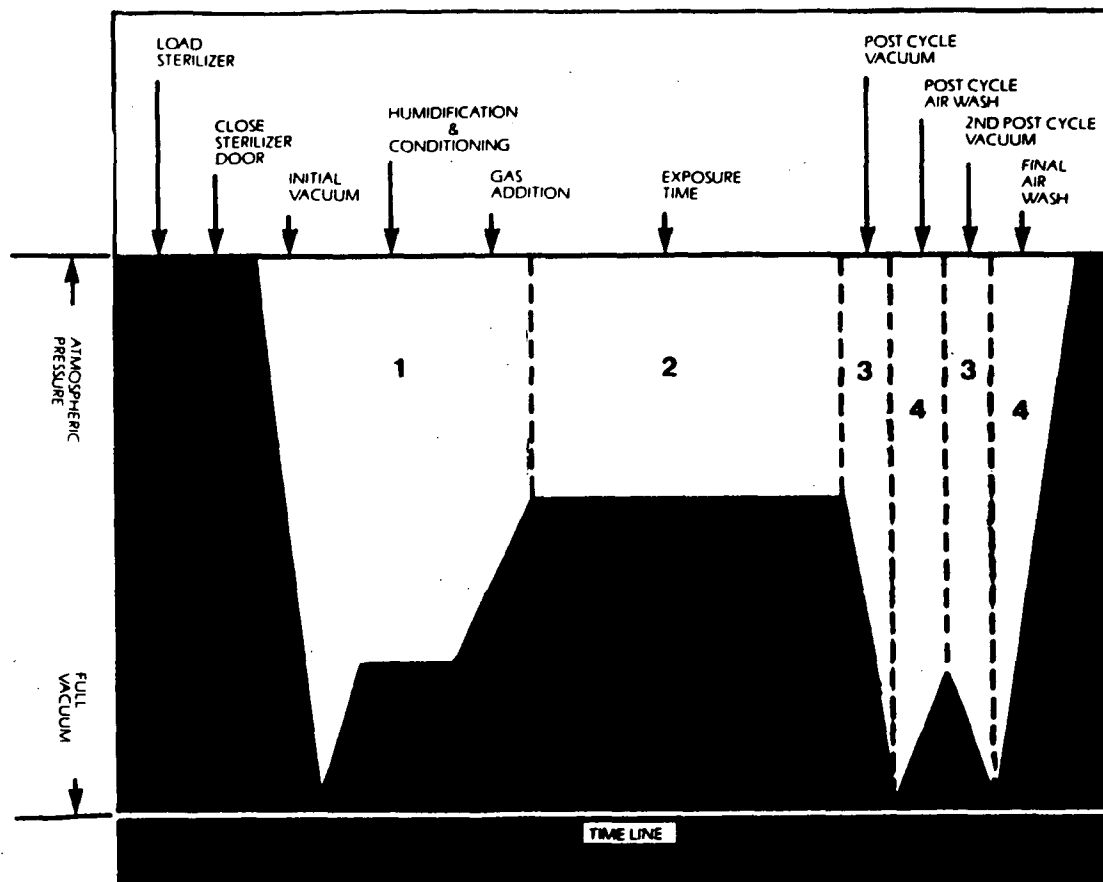


1. PRESTERILIZATION CONDITIONING
2. STERILIZATION

3. EVACUATION
4. AIR WASH

Figure 3-2. Sterilization cycle for 12/88.
(Courtesy of Union Carbide Corporation, Linde Division.)⁷

3-13



1. PRESTERILIZATION CONDITIONING
2. STERILIZATION

3. EVACUATION
4. AIR WASH

Figure 3-3. Sterilization cycle for pure EO.
(Courtesy of Union Carbide Corporation, Linde Division.)⁷

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sterilized. Certain products require a longer drawdown time because they are damaged by sudden pressure changes. The chamber temperature is then adjusted to between 38° and 54°C (100° and 130°F). A higher temperature increases the diffusion rate of EO into the products and, thus, reduces the time the products must be exposed to the sterilant gas to ensure proper sterilization. Finally, the relative humidity is raised to about 45 percent by injecting steam. Proper humidification is important to the process because the susceptibility of microorganisms to the sterilant gas is increased under moist conditions.⁷

3.2.1.3.2 Sterilization. The sterilant, which is supplied as a liquid, is vaporized and introduced into the chamber to achieve the desired concentration of EO (600 parts per million [ppm]).⁷ The chamber pressure depends on the type of sterilant gas used. Pure EO is used under vacuum pressures of about 51 kPa (7.35 psia); the 12/88 mixture is used at pressures of about 170 kPa (24.7 psia). The pressure is held for about 4 to 6 hours. This exposure time is dependent on the temperature, pressure, humidity level, type of sterilant gas, and products being sterilized. For example, porous products require shorter exposures than nonporous products. Also, some bacteria are more resistant to EO and take longer to destroy.

3.2.1.3.3 Evacuation. Following sufficient exposure time, the sterilant gas is evacuated from the chamber with a vacuum pump. (If sterilization is performed at a pressure greater than atmospheric, the chamber is often allowed to vent to atmospheric pressure before using the vacuum pump to evacuate the chamber.) Typical evacuation pressures are 13 kPa (1.9 psia) for 12/88 gas and 3 kPa (0.4 psia) for pure EO. This postcycle vacuum phase typically lasts about 10 minutes.

3.2.1.3.4 Air wash. The pressure in the chamber is brought to atmospheric pressure by introducing air (when nonflammable sterilant gases are used) or either nitrogen or CO₂ (when flammable sterilant gases are used). The combination of evacuation and air wash phases is repeated from two to four times

to remove as much of the EO from the product as possible. Each air wash typically lasts 2 to 15 minutes.

The purpose of the air wash is to allow residual EO to diffuse from the product. Removal of EO from the product during the air wash helps meet Food and Drug Administration (FDA) guidelines on residual EO levels for medical devices, EPA residual tolerances for agricultural products, and the OSHA standard for exposure in the workplace.

3.2.1.3.5 Chamber exhaust. Prior to unloading the sterilizer, the chamber door is automatically cracked, and the chamber exhaust is activated. The chamber exhaust is an exhaust system that evacuates EO-laden air from the chamber prior to unloading and while the chamber is being unloaded (and reloaded). The chamber exhaust typically consists of a butterfly valve in the ductwork that opens automatically and a roof-mounted blower that automatically switches on and pulls fresh air through the chamber. A chamber face velocity of 30.5 m/min (100 ft/min) is generally maintained, producing a chamber exhaust flow rate of 28 to 85 m³/min (1,000 to 3,000 ft³/min), depending on chamber size. This process usually begins 15 minutes prior to unloading and continues during loading and reloading.¹⁴

The chamber exhaust is responsible for removing EO from the void space in the sterilizer chamber, not the product. Use of the chamber exhaust assists some facilities in meeting the EO worker exposure levels set by OSHA. Facilities that use conveyors to load and unload the chamber, as well as facilities that do not have problems meeting OSHA worker exposure levels, may not use chamber exhausts.

3.2.1.3.6 Aeration. After the last air wash, the sterile products are placed in an aeration room and kept there for several hours to days depending on the product. The purpose of aeration is to allow further diffusion of residual EO from the products prior to shipping in order to comply with the FDA and EPA residual EO guidelines. Ethylene oxide concentrations in the aeration room are maintained at relatively low levels by ventilating the room at a rate of about 20 air changes per hour.

Recent information from industry contacts indicates that some commercial sterilization facilities are aerating some or all of the sterile products in heated enclosed aeration units. In comparison to traditional warehouse-type aeration rooms, these units are smaller in volume ($<70 \text{ m}^3$ [2500 ft^3]) with much lower ventilation rates. Consequently, the EO concentrations are usually higher than the 1 ppmv OSHA standard. However, worker exposure is reduced by not opening the door until the EO concentration drops and by limiting the frequency of opening the aeration room door. The main purpose of this type of aeration process is to increase the diffusion rate of EO out of the sterile product (by increasing the temperature) and, thus, reduce the aeration time.

Facilities that sterilize products infrequently may aerate in the sterilization chamber. Two basic chamber aeration processes are used. The first process involves cycling the chamber between atmospheric pressure and a slight vacuum pressure (i.e., a pressure of about 94 kPa [13.7 psia]) several times over a 12- to 24-hour period. The length of these cycles depends on the chamber size and vacuum pump capacity. The second process involves drawing an extreme vacuum (about 0.6 kPa [0.1 psia]) in the chamber and holding the vacuum for 24 to 48 hours.

Some commercial sterilization facilities with small sterilizers (less than 1 m^3 [40 ft^3]) use aeration chambers (or cabinets), which are similar to the sterilization chambers in size and design. These facilities typically aerate products for about 24 hours.

3.2.2 Single-Item Sterilization System

Four of the 196 commercial sterilization facilities represented in the 1989 EPA CS data base (2 percent) reported the use of a single-item sterilization system.^{1,2} Three of these facilities use the Sterijet® system manufactured by H. W. Andersen Products; one facility uses another patented system that is similar to the Sterijet® system.² In contrast to the bulk sterilization chambers used by most commercial sterilization facilities, these systems are designed to sterilize

small individual items (such as medical equipment supplies) in sealed pouches. Marketing of these systems is primarily focused on hospital sterilization.¹⁵

These single-item sterilization systems consist of (1) a machine that delivers the sterilant gas through a nozzle, (2) flexible plastic pouches, and (3) an aeration cabinet. The process involves the following steps. The product to be sterilized is placed in a plastic pouch. With the open ends of the pouch sealed around the nozzle, a slight vacuum is drawn in the pouch followed by injection of a premeasured quantity of sterilant gas. The amount of sterilant gas injected depends on the size of the pouch. After the gas is injected, the nozzle is automatically withdrawn, and the pouch is heat sealed. The sealed pouches are placed directly into an aeration cabinet or temperature-controlled aeration room. The enclosed product is sterilized prior to the escape of the gas through the pouch, which is designed to retain the EO long enough to ensure proper sterilization. The products are sterilized for approximately 12 hours at about 50°C (122°F) and aerated for 36 hours.¹⁵

Another type of single item sterilization system consists of (1) ampule-delivered EO sterilant gas, (2) flexible plastic pouches, (3) a sterilization cabinet, and (4) an optional aeration cabinet.¹⁶ This process involves the following steps. The product to be sterilized is wrapped in gas permeable packaging and placed in a plastic pouch along with an ampule containing the sterilant gas. The pouch is placed in the sterilization cabinet, and the ampule is broken to release the sterilant gas. The pouch is then sealed, and the cabinet closed to allow sufficient time for sterilization of the materials. After the sterilization cycle is complete, the cabinet door and plastic pouch are opened, and the materials are unloaded. Depending on the characteristics of the materials sterilized, they may be placed in an aeration cabinet to allow for the offgassing of residual EO. The products are typically sterilized for approximately 12 hours at room temperature and atmospheric

pressure, and aerated for approximately 12 hours at 50°C (122°F) at atmospheric pressure (if an aeration cabinet is used).¹⁶

At least one vendor does offer an optional or retrofit ventilation hood to control worker exposure to EO when loading/unloading the sterilizer, and while sterilization occurs. This device causes fresh air to be pulled past the chamber by a roof-mounted blower; however, this system does not provide any evacuation of the sterilization cabinet itself.¹⁶

3.2.3 Spice Fumigators

The process for spice fumigators is essentially the same as bulk sterilization.¹⁷ The spices are typically stored in fiber drums lined with a plastic insert, which is closed with twist tie; lids are then placed on the drums. Alternatively, the spices may be stored in large bags or totes. The drums, bags, or totes are loaded into the sterilization chamber on wooden pallets, typically via a conveyor. Depending on how densely packed the spice is, a long, hollow spike punctured with many holes may be driven into the spice to allow the EO to penetrate through the bag drum, or tote. Ethylene oxide is then added to the chamber. The length of the sterilization cycle depends on the product's susceptibility to adequate kill rates. Ethylene oxide's effectiveness is different for different spices. Following evacuation of the sterilization chamber, and subsequent air washes, the spices are removed from the sterilization chamber and placed in an aeration room. Aeration typically takes 2 hours.¹⁷

3.2.4 Library and Museum Fumigators

Library and museum fumigation is accomplished using essentially the same process as for bulk sterilization. However, the amount of ethylene oxide used each year by these facilities is much lower than that used by the typical bulk sterilizers. These library and museum fumigators are typically operated only one to two times a month.¹⁸⁻²¹ Additionally, several museums and libraries are discontinuing their use of ethylene oxide for fumigation because of (1) the recent OSHA worker exposure regulations and (2) problems associated with the long aeration

times needed when fumigating organic materials with EO (most museums and libraries do not have the space needed for adequate aeration of organic materials, such as wood [up to 1 month], because these materials readily absorb much of the EO used in the fumigation process).²²⁻²⁴ Some museums have switched to using sulfuryl fluoride as a fumigant.^{22,23} Other museums are accepting objects from other museums and libraries to be fumigated with EO in their fumigator.²⁵

3.2.5 Beehive Fumigators

The process for beehive fumigators is essentially the same as bulk sterilization; however, a unique feature of the fumigators warrants a separate discussion. Whereas the sterilization processes described above are performed at one location, the eight State departments of agriculture represented in the EPA sterilization data base use portable chambers to fumigate beehives at numerous and variable locations in each of the six States.² The State departments of agriculture use an EO/CO₂ sterilant gas mixture. Typically, a garden hose is connected to the fumigation chamber and is placed along the ground for venting the sterilant gas during the evacuation phase of the sterilization cycle. After the evacuation, the beehive is removed from the chamber and aerated in the open air.

3.3 EMISSION SOURCES

The four principal sources of EO emissions from sterilization/fumigation processes are (1) the sterilizer vent(s) (i.e., the vent on the vacuum pump gas/liquid separator), (2) the sterilization chamber vacuum pump drain (assuming that a once-through, water-ring vacuum pump is used), (3) the chamber exhaust vent(s), and (4) the aeration room vent(s). A schematic of these emission sources is shown in Figure 3-4. Other potential emission sources are equipment leaks and storage and handling. (For the purposes of developing emission estimates, and because bulk sterilization processes are the main source of emissions, emission sources were assumed to be the same for all stationary sterilization processes [i.e., bulk and single-item and the 55-gallon drums]).

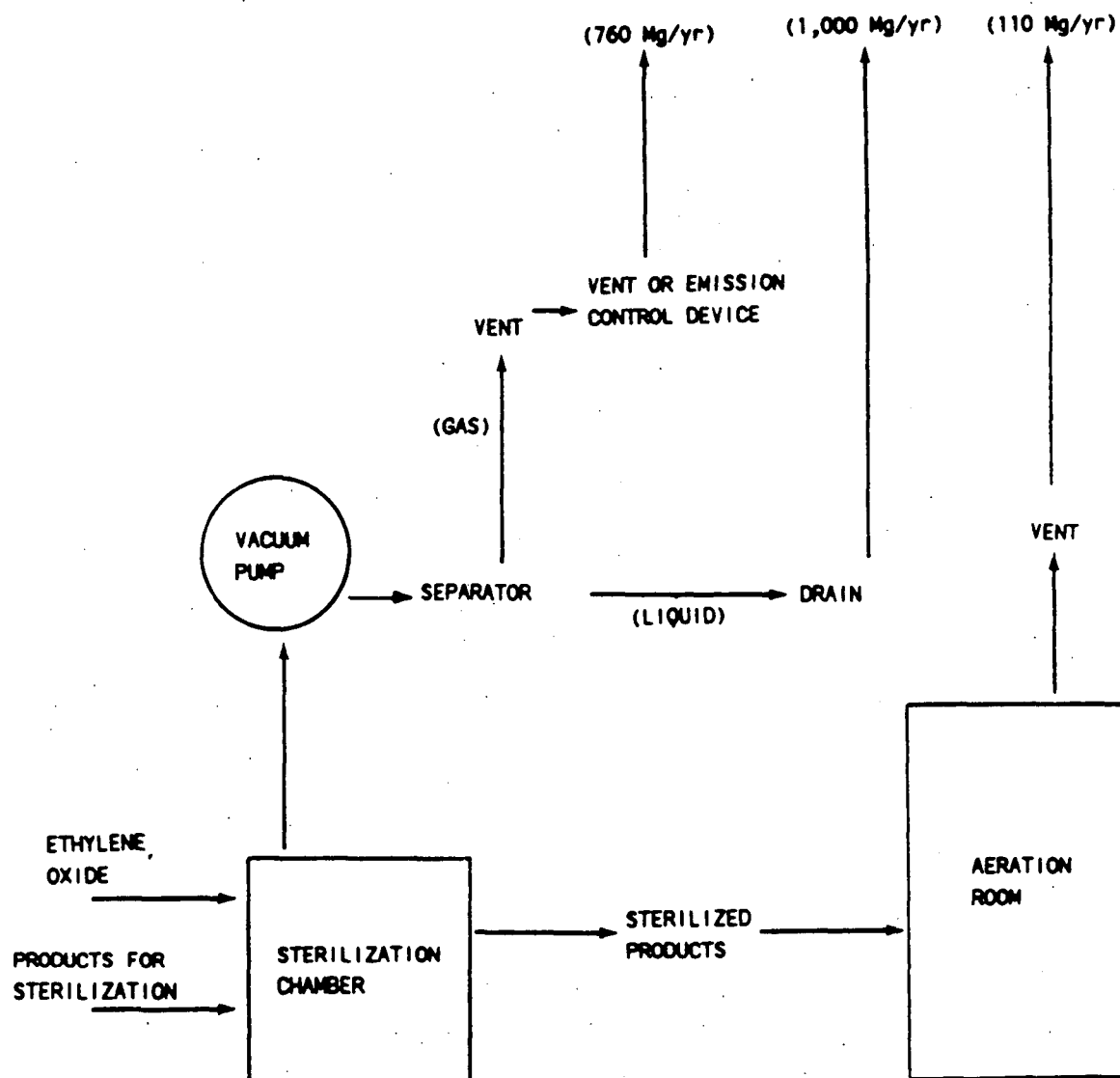


Figure 3-4. Schematic of emission sources at commercial sterilization facilities.

3.3.1 Sterilization Chamber Vents

Sterilization chamber vent emissions are dependent on the type of vacuum pump used to evacuate the sterilizer. Once-through, liquid-ring design vacuum pumps that use water as the working fluid discharge a mixture of chamber gas and water to a centrifugal gas/liquid separator. In the separator, gaseous EO is directed to a vent and emitted to the atmosphere. The liquids from the separator are discharged to a drain. (Full-sealant recovery [i.e., oil-sealed or recirculating water] vacuum pumps do not produce drain emissions of EO.) Sterilizer vent emissions also include emissions associated with venting the chamber from a positive pressure before evacuating with a vacuum pump.

3.3.2 Sterilization Chamber Vacuum Pump Drains

If a once-through, water-ring vacuum pump is used to evacuate the chamber, some of the EO evacuated from the chamber enters the liquid-phase separator line with the vacuum pump water. Although some EO may be hydrolyzed to ethylene glycol, the conversion rate at ambient temperatures is extremely slow, requiring weeks for completion (see Figure 3-5).⁸ Also, EO is rapidly released from an aqueous solution when agitated.²⁶ Therefore, virtually all of the EO that dissolves in the vacuum pump water is emitted from the water. The absorbed EO may be released at the 1-inch air break between the liquid pipe and drain (required by local plumbing codes) or may diffuse into other areas of the building as the water passes through the drain system. Any remaining EO would desorb into the head space of the sewer pipes (possibly creating flammable mixtures with air) and be emitted as it passes through the sewer or waste treatment systems.^{6,8}

3.3.3 Chamber Exhaust Vent

Chamber exhaust emissions consist of EO that remains in the sterilizer chamber void space (surrounding the product) after the sterilization cycle is completed. Product off-gassing in the sterilizer is a negligible contributor to this emission source.²⁷ Therefore, the chamber exhaust emissions are assumed to be only EO trapped in the sterilizer void space.

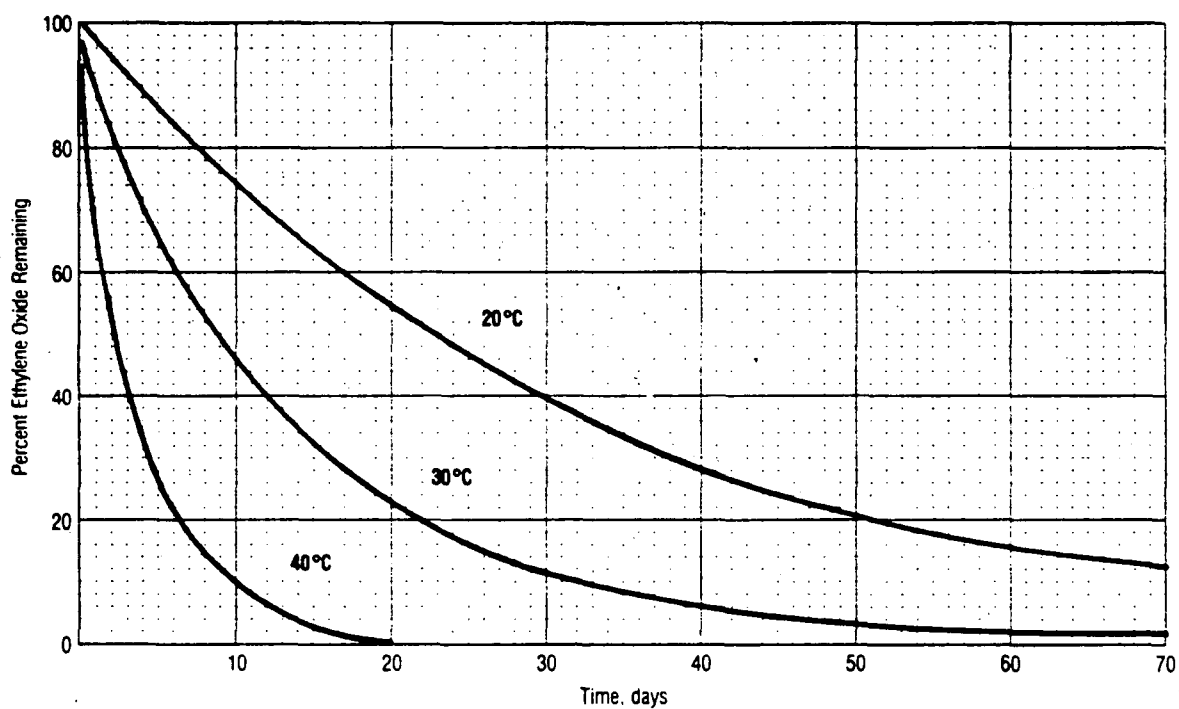


Figure 3-5. Hydrolysis rates of dilute, neutral aqueous solutions of ethylene oxide. (Courtesy of Union Carbide Corporation, Ethylene Oxide/Glycol Division.)⁸

3.3.4 Aeration Room Vent

All emissions from residual EO in the product are referred to as aeration room vent emissions. As residual EO diffuses out of the sterile products in the aeration room or is emitted to the sterilization room when the chamber door is opened, it is emitted to the atmosphere via room ventilation. High ventilation airflow rates are used to maintain EO concentrations below the OSHA limit.

3.3.5 Equipment Leaks

Although equipment component counts (number of flanges, valves, etc.) were not obtained for the commercial sterilization facilities, observations made during site visits indicated that the number of components is small. However, control of equipment leaks may be important to meet the 1 ppmv OSHA standard. For the purposes of this analysis, equipment leak emissions are assumed to be negligible.

3.3.6 Storage and Handling

Ethylene oxide at commercial sterilization facilities is typically stored in pressurized cylinders rather than bulk containers. Therefore, material losses associated with loading and unloading bulk quantities of EO and storage tank breathing losses would not occur. Although bulk storage of sterilant gas at sterilization facilities is rare, at least one commercial sterilization facility stores bulk quantities of 12/88 in a pressure vessel. During transfer of the 12/88 from the tank truck to the pressure vessel, the vessel and the tank truck are vapor balanced. Therefore, emissions during transfer are expected to be negligible. Also, because the storage tank is a pressure vessel, no emissions should occur during routine operation. Consequently, commercial sterilization facilities are likely to have negligible storage and handling emissions.

3.4 EMISSION ESTIMATES

3.4.1 Commercial Sterilization Facilities

The emission estimate for commercial sterilization facilities is based on the facility-specific annual EO usages and emission control levels reported in the 196 responses to the HIMA survey, the 1986 EPA ICR, and the July 1989 Section 114

letter.^{1,2} Eight of the 196 facilities are State departments of agriculture that operate a total of 10 mobile beehive fumigator units; these units are not included in these or subsequent analyses unless otherwise stated. (These 10 fumigation units use a total of 0.46 megagrams per year (Mg/yr) (1,015 pounds per year [lb/yr]) of EO, all of which is reportedly uncontrolled.)

Average EO emissions from the remaining 188 commercial sterilization facilities, based on total sterilizer volume, are presented in Table 3-6. The total amount of EO used by these 188 commercial sterilization facilities is 1,920 Mg/yr (4.23 million lb/yr); approximately 42 percent (i.e., 809 Mg/yr [1.78 million lb/yr]) of this amount is controlled. Therefore, the EO emission estimate for the 188 facilities represented in the 1989 EPA CS data base is 1,111 Mg/yr (2.45 million lb/yr).¹⁻⁴ Of this amount, it is estimated that 667 Mg/yr (1.47 million lb/yr) are emitted from sterilizer vents; 312 Mg/yr (688,000 lb/yr) are emitted from sterilization chamber vacuum pump drains; 38 Mg/yr (84,000 lb/yr) are emitted from chamber exhaust vents; and 57 Mg/yr (126,000 lb/yr) are emitted from aeration room vents (see Figure 3-4). These estimates were developed using the HIMA survey, the EPA ICR responses, the Section 114 letter (July 1988 and July 1989) responses, and the following assumptions:

1. All of the EO used in the sterilization process is evacuated from the sterilization chamber or released from the product during postevacuation processes.
2. Within each facility, EO emissions are distributed among four emission points. The four emission points and the percentage of total EO emissions allocated to each are:
 - a. Sterilizer vent(s)--50 percent;
 - b. Sterilization chamber vacuum pump drain (if applicable)--45 percent;
 - c. Chamber exhaust vent(s)--2 percent; and
 - d. Aeration room vent(s)--3 percent.

This 50/45/2/3-percent split is based on industry estimates, limited test data, and engineering judgment.^{28,29}

TABLE 3-6. AVERAGE EMISSIONS FROM COMMERCIAL
STERILIZATION FACILITIES--EPA COMMERCIAL STERILIZATION
DATA BASE¹⁻⁴

Total chamber volume at facility, m ³ (ft ³)	No. of facilities	Mean EO use, kg/yr (lb/yr)	Mean EO emissions, kg/yr (lb/yr) ^{a b}
< 11 (< 400)	87	580 (1,300)	520 (1,200)
11-56 (400-2,000)	71	6,500 (14,000)	4,200 (9,300)
> 56 (> 2,000)	38	37,000 (82,000)	20,000 (45,000)

^aMean emissions are less than mean EO use because of existing controls.

^bEmissions from all sources (i.e., sterilizer vent, vacuum pump drain, aeration).

3. For the uncontrolled sterilization chambers, all of the EO that enters the chamber (except 3 percent, if the aeration room is controlled) is released to the atmosphere. For the 79 sterilization chambers with emission control devices, the chamber vent emissions are assumed to be controlled at the following efficiencies:

a. 99.0 percent for acid/water scrubbers and catalytic oxidizers;

b. 99.0 percent for flares (given the chemical/ physical characteristics of ethylene oxide, its high combustability, and the extremely weak nature of the oxide bond, it is reasonable to assume that emissions of ethylene oxide will be controlled at an efficiency of 99 percent in flares rather than the generally EPA-accepted efficiency for flares of 98 percent); and

c. The facility-reported efficiency for other control devices.

4. All facilities that control sterilizer vent emissions with acid/water scrubbing, catalytic oxidation, flaring, or condensation/ reclamation control devices are assumed to have recirculating-fluid vacuum pumps and, thus, no drain emissions from those chambers. (One facility that uses a different control technology than those described above is assumed to have a once-through water-sealed pump). All uncontrolled facilities are assumed to have once-through water-sealed pumps unless data are available to indicate otherwise.

5. At facilities that have once-through water-sealed vacuum pumps, all of the EO that dissolves in the vacuum pump water subsequently enters the drain and is assumed to be emitted uncontrolled to the atmosphere at an outdoor ground-level drain near the facility. This assumption is consistent with test data that suggest EO is rapidly released from an aqueous solution when agitated.²⁶

6. Facilities that have a total sterilizer volume greater than 7 m³ (>250 ft³) are assumed to have chamber exhausts on all sterilizers. Chamber exhaust emissions are assumed to equal

2 percent of the total EO use and to be released uncontrolled to the atmosphere.²⁹

7. At each facility (except for three facilities that have aeration room controls), all of the EO that enters the aeration room(s) vent is released uncontrolled to the atmosphere.

3.5 CURRENT REGULATIONS

3.5.1 Occupational Safety and Health Administration Standard

In 1984, OSHA established a permissible exposure limit for occupational exposure to EO of 1 ppmv determined as an 8-hour time-weighted average (TWA) concentration. In addition, an action level of 0.5 ppmv as an 8-hour TWA was established as the level above which employers must monitor employee exposure.³⁰ In April 1988, OSHA established a short-term excursion limit (EL) for occupational exposure to EO emissions of 5 ppmv averaged over a 15-minute sampling period.³¹

3.5.2 State Regulations

Existing State regulations for EO are summarized in Table 3-7. Several States are currently regulating EO or developing air toxics programs.³²⁻³⁸

TABLE 3-7. STATE REGULATIONS FOR ETHYLENE OXIDE EMISSIONS²²⁻²⁸

State	Regulatory description															
California ^a	<ul style="list-style-type: none">Control is based on annual EO usage<table><tr><th>Annual usage, lb</th><th>Sterilizer control</th><th>Aeration control</th></tr><tr><td><25</td><td>No control</td><td>No control</td></tr><tr><td>25-600</td><td>99%</td><td>No control</td></tr><tr><td>600-5,000</td><td>99.9%</td><td>95%</td></tr><tr><td>>5,000</td><td>99.9%</td><td>99%</td></tr></table>	Annual usage, lb	Sterilizer control	Aeration control	<25	No control	No control	25-600	99%	No control	600-5,000	99.9%	95%	>5,000	99.9%	99%
Annual usage, lb	Sterilizer control	Aeration control														
<25	No control	No control														
25-600	99%	No control														
600-5,000	99.9%	95%														
>5,000	99.9%	99%														
Colorado	<ul style="list-style-type: none">Regulate as a volatile organic compound (VOC).Reasonably available control technology (RACT) required for new sources.															
Connecticut	<ul style="list-style-type: none">Best available control technology (BACT) required for all new or modified sources exceeding a maximum allowable stack concentration (MASC).MASC is calculated using exhaust gas flow rate, stack height, and the distance from the discharge point to the property line. MASC would be exceeded for industrial sterilizers using typical sterilization cycles. Therefore, BACT required on new or modified sources. Existing sources exceeding the maximum allowable ambient concentration of 0.01 ppm have 3 years to comply with orders given by the Connecticut Department of Environmental Protection.															
Florida ^a	<ul style="list-style-type: none">Maximum risk level of 10⁻⁶ for new or modified sources.															
Michigan ^a	<ul style="list-style-type: none">BACT for all new sources. Requires emissions be indelectable or subjected to risk analysis (maximum allowable risk level is 10⁻⁶). For industrial sterilizers using typical sterilization cycles, a control efficiency based on a risk assessment analysis would be greater than 99 percent by weight.															
Missouri	<ul style="list-style-type: none">Regulate as a VOC.															
New Jersey	<ul style="list-style-type: none">Regulate as a VOC.BACT required for new or modified sources.															
New York ^b	<ul style="list-style-type: none">New or modified sources must receive 99 percent control or greater, or BACT (also at permit reviews)Maximum annual impact must not exceed guideline Acceptable Ambient Level (AAL) of 6.67 µg/m³ (a revised AAL of 0.019 µg/m³ is anticipated for the next edition of Air Guide-1 [to be released by 01/90]).Certificate of operation includes the following statement:<p>"Should significant new scientific evidence from a recognized institution result in the decision by DEC that lower ambient levels must be established, it may be necessary to reduce emissions from this source prior to the expiration of this Certification of Operation."</p>															
Oklahoma	<ul style="list-style-type: none">Maximum ambient air concentration at property line is 1/100 of TLV.															
Puerto Rico	<ul style="list-style-type: none">Regulate as a VOC.Emission controls required for emissions greater than 3 lb/h or 15 lb/d.															
Rhode Island ^b	<ul style="list-style-type: none">Maximum risk level of 10⁻⁶ for new and existing sources.If BACT is used, may consider 10⁻⁵ risk level.															
Tennessee	<ul style="list-style-type: none">Regulate under standards for process and nonprocess emissions.															
Texas	<ul style="list-style-type: none">BACT required for all new sources.															
Utah	<ul style="list-style-type: none">BACT required for all new or modified sources. BACT requirements to go into effect for existing sources.Following the programs developed in New York.															
Vermont	<ul style="list-style-type: none">Regulate as a VOC.															
Virginia	<ul style="list-style-type: none">For any 24-hour concentration exceeding 1/100 of the TLV-TWA both existing and new facilities are required to control emissions as directed by the Virginia Air Pollution Control Board.															
Wyoming	<ul style="list-style-type: none">BACT required for all new sources.Controls must meet AAL at property line.															

^aInformation obtained from State contacts in May 1990.

^bInformation obtained from State contacts in February 1989. All other information is from 1986 through 1987 data.

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4..0 EMISSION CONTROL TECHNIQUES

This chapter describes the techniques available to control ethylene oxide (EO) emissions from bulk sterilization and single-item sterilization processes. Alternatives to EO sterilization, retrofit considerations, and the impacts of chlorofluorocarbon (CFC) regulation on EO emission controls are also discussed.

4.1 BULK STERILIZATION PROCESSES

Discussed below are techniques available to control emissions of ethylene oxide (EO) from the four principal sources of emissions from bulk sterilization processes:

1. The sterilizer vent(s) (i.e., the vent on the vacuum pump gas/liquid separator);
2. The sterilization chamber vacuum pump drain;
3. The chamber exhaust vent; and
4. The aeration room vent.

4.1.1 Sterilization Chamber Vent Emissions

Three primary techniques are used to control EO emissions from sterilizer vents: hydrolysis, oxidation, and condensation. Ethylene oxide is catalytically hydrolyzed to form ethylene glycol; thermal or catalytic oxidation decomposes EO into carbon dioxide and water; and condensation allows the recovery of the sterilant gas mixture. A fourth control technique for sterilizer vents is a gas/solid reactor system that chemically reacts with EO and binds it to the solid packing of the reactor.¹

Table 4-1 shows the emission control techniques and devices for sterilizer vent emissions used by the controlled facilities represented in the EPA data base (refer to Chapter 3 for a description of the contents and origin of the data base). Forty of the 188 commercial sterilization facilities (21 percent) in

TABLE 4-1. ETHYLENE OXIDE EMISSION CONTROL DEVICES FOR
STERILIZER VENTS--EPA COMMERCIAL STERILIZATION DATA BASE^{2,3,5}

Emission control technique and device	Control efficiency, (percent) ^a	No. of facilities (percent)	No. of chambers (percent)	Cumulative chamber size, m ³ (ft ³)	EO usage/facility, Mg/yr (lb/yr)
Hydrolysis					
Packed scrubber	99.0 ^b	21 (11)	78 (19)	7 - 274 (350 - 9,900)	0.8 - 84 (1,800 - 180,000)
Reaction/detoxification tower	99.0 ^b	7 (4)	15(4)	8 - 45 (300 - 1,600)	2.1 - 49 (5,000 - 110,000)
Caustic scrubber	50	1 (0.5)	2 (0.5)	9 (320)	0.2 (400)
Oxidation					
Flare	98.0 ^c	3 (2)	6 (1.5)	11 - 229 (400 - 8,180)	25 - 90 (54,000 - 197,000)
Catalytic oxidizer	99.0	2 (1)	2 (0.5)	4 - 18 (130 - 660)	0.5 - 7 (1,000 - 15,000)
Condensation					
Condensation/reclamation system	50.0 - 83.0	6 (3)	16 (4)	32 - 132 (1,160 - 4,720)	7 - 127 (15,000 - 280,000)
Total		40 (21) ^d	119 (29) ^e		1,020 (2,240,000) ^f

^aControl efficiencies are those reported by the 188 commercial sterilization facilities represented in the EPA data base and are not necessarily supported by EPA-sponsored test data.

^bAlthough the 21 commercial sterilization facilities that use scrubbers reported control efficiencies ranging from 96.0 to 99.9 percent, a detailed review of the available test data for acid-water scrubbers indicates that 99.0 percent is the maximum removal efficiency that can be achieved on a continuous basis.¹⁶

^cAlthough the two commercial sterilization facilities that use flares reported destruction efficiencies of 99.0 and 99.7 percent, the EPA's position is that flares operated within specified conditions of waste gas heat content and flare exit velocity will achieve at least 98 percent destruction efficiency.²⁵

^dTotal number of facilities = 188.

^eTotal number of chambers = 404.

^fRepresents 53 percent of the total EO used by the 188 commercial sterilization facilities represented in the EPA data base.

the data base reported the use of a control device for sterilizer vent emissions. Twenty-eight of these 40 facilities use one emission control device for multiple chambers by manifolding the chamber vents and staggering the evacuation of the sterilant gas from the chambers. The remaining 12 facilities control emissions from single chambers.²⁻⁵

Nine additional commercial sterilization facilities reported the use of a neutral-water scrubber to control EO vent emissions. Neutral-water scrubbers reduce EO vent emissions by "washing" a portion of the EO to the drain (facilities reported 20 to 100 percent of the total EO emissions from the sterilizer chamber were "controlled" by a neutral-water scrubber).²⁻⁵ Some of the EO that is washed to the drain may be converted by hydrolysis to ethylene glycol; however, the conversion rate of EO to ethylene glycol in neutral water at ambient temperatures is extremely slow, requiring weeks for completion.⁶ Since EO is rapidly released from an aqueous solution when agitated, the vast majority of the EO washed to the drain is expected to off-gas uncontrolled from the air break in the drain line, sewer lines, or the waste water treatment system.⁶⁻⁸ Because the use of neutral-water scrubbers merely changes the EO emission source, these scrubbers are not discussed here as a control technique.

4.1.1.1 Hydrolysis. Hydrolysis is the most common EO emission control technique used by commercial sterilization facilities.²⁻⁵ This technique is applicable for both pure EO and EO/inert gas mixtures such as 12/88 (12 percent by weight EO and 88 percent by weight dichlorodifluoromethane [CFC-12]) and 10/90 (10 percent by weight EO and 90 percent by weight carbon dioxide [CO₂]).

Ethylene oxide can be hydrolyzed under relatively mild conditions to ethylene glycol products (without affecting the inert gas) as shown in the following reaction:



Ethylene
oxide

Ethylene
glycol

Polyethylene
glycols

Ethylene oxide will hydrolyze in neutral water, but this reaction is very slow. (The half-life of EO in neutral water at ambient temperatures is approximately 14 days.)⁸ The reaction rate is increased in an acidic or basic solution. The reaction is approximately two orders of magnitude faster under acidic conditions than under basic conditions, making acid hydrolysis the preferred method. Twenty-eight of the 188 commercial sterilization facilities represented in the EPA data base reported using acid-water scrubbers; one facility reported using caustic scrubbers to control EO emissions.²⁻⁵

4.1.1.1.1 Packed scrubbers. Figure 4-1 is a schematic of a packed scrubbing system used to control EO emissions. The system consists of a countercurrent packed tower, a reaction vessel, and a holding tank. In the countercurrent tower, the sterilant gas is contacted with an acidic water solution, generally aqueous sulfuric acid. Because EO is extremely water soluble, most of the EO is absorbed into the scrubber liquor. Next, the liquor is sent to the reactor vessel, which is a small storage tank operated at atmospheric pressure, to complete the hydrolysis of EO. After the reaction is complete, the liquor is sent to the storage vessel. The liquor in the storage vessel is recirculated to operate the tower until the concentration of the ethylene glycol in the liquor reaches a predetermined weight percentage, past which point the scrubber efficiency declines. Manufacturers of packed scrubbing systems suggest that the scrubbing liquor is spent when the solution is 30 to 40 percent by weight ethylene glycol.^{9,10} Possible methods of determining when the liquor needs replacing include liquid level indicators or specific gravity detectors in the tank. (Both parameters increase as the amount of ethylene glycol increases.) Alternatively, the amount of EO charged to the sterilizer can be used to determine the liquor changeout point. The spent solution is neutralized and

4-5

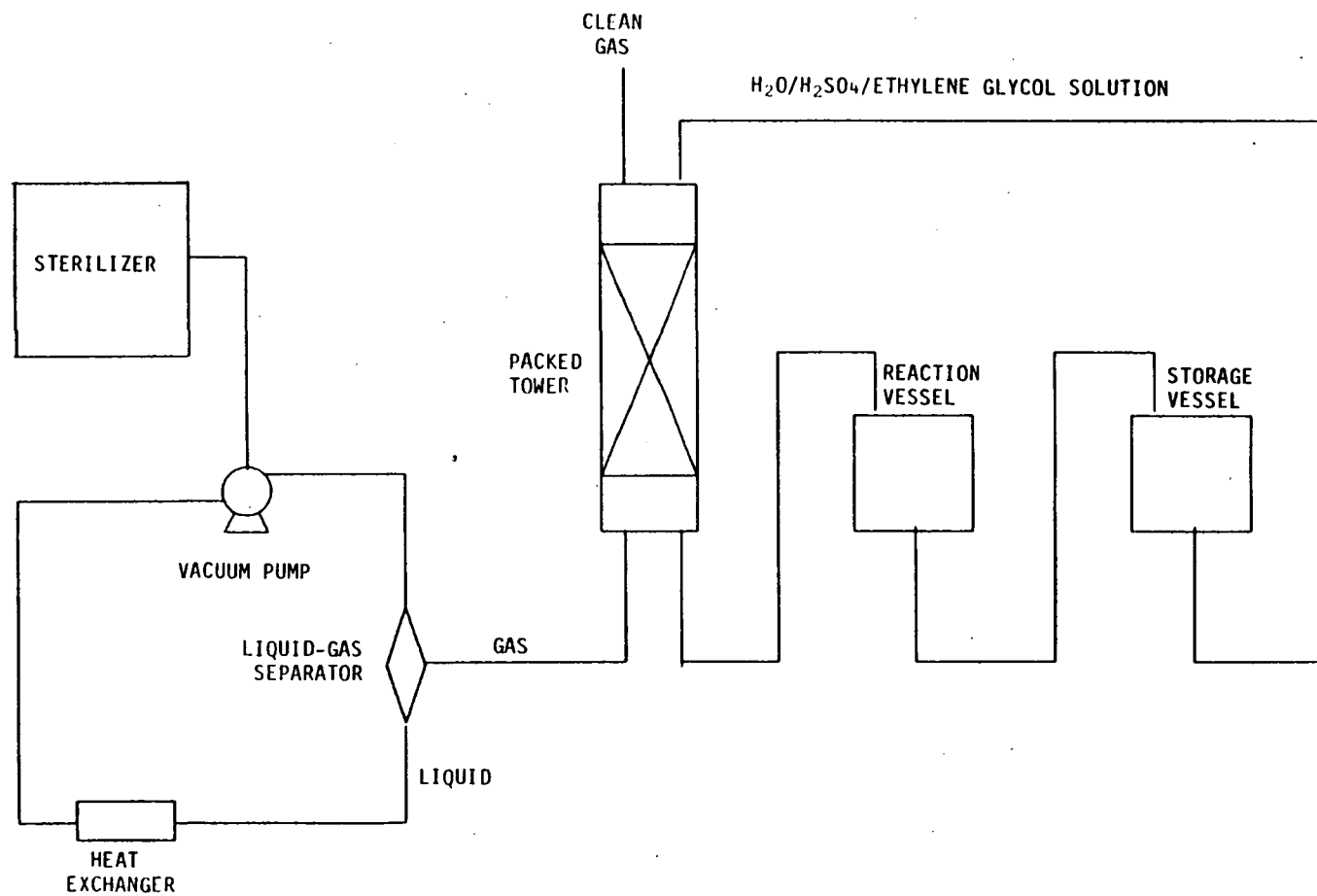


Figure 4-1. Countercurrent packed scrubbing system.

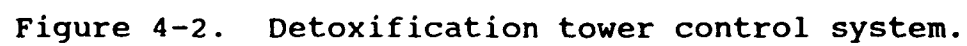
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then disposed or sold. (See Section 4.1.1.1.3 for a more detailed discussion of waste disposal.) Generally, sodium hydroxide is used to neutralize the glycol solution; sodium carbonate can also be used.

Countercurrent packed scrubbers are used by commercial sterilization facilities with sterilizers ranging from 1.1 cubic meters (m^3) (40 cubic feet [ft^3]) to 170 m^3 (6,000 ft^3). Ethylene oxide use at these commercial sterilization facilities ranges from 0.8 megagrams per year (Mg/yr) (2,000 pounds per year [lb/yr]) to 84 Mg/yr (180,000 lb/yr).^{2,3,5}

Manufacturers of countercurrent packed scrubbers designed to control EO emissions from sterilizer vents claim EO removal efficiencies greater than 99 percent.^{1,9,11} For a 12/88 sterilant-gas mixture, the average EO removal efficiency for three tests was 99.0 percent by weight (individual test results were 99.0, 98.7, and 99.4 percent).¹² These tests were conducted using a scrubber that was designed to achieve an EO removal efficiency of 99 percent. A representative from the manufacturer of the tested acid-water scrubber stated that the company can design scrubbers to achieve virtually any EO removal efficiency with any type of sterilant gas.¹³ The results of an EPA-sponsored test on another acid-water scrubber designed by this company indicated an EO removal efficiency greater than 99.9 percent for 12/88.¹⁴ For pure EO, the EO removal efficiency was greater than 99.98 percent for each of four tests performed at two facilities.^{12,15} However, a detailed review of the available test data indicates that 99.0 percent is the highest EO removal efficiency that can be achieved on a continuous basis based on limited data at various EO concentrations.¹⁶

4.1.1.1.2 Reaction/detoxification towers. Another acid hydrolysis scrubbing technique for EO emission control is a reaction, or detoxification, tower. A schematic of this system is shown in Figure 4-2. The reaction/detoxification tank holds a sulfuric acid solution of pH 0.5 to 2.5. As the sterilant gas bubbles upward through the acidic liquor, EO is absorbed, and catalytically hydrolyzed to ethylene glycol. The gas stream then



flows through the liquid surface and a demister. The demisting pad prevents acid mist from exiting with the scrubbed gas and provides a final hydrolysis reaction site for any EO remaining in the gas stream. Inert gases (i.e., CFC-12 and CO₂) are exhausted unreacted to the atmosphere. After ethylene glycol builds up in the stream to a maximum recommended level of 60 percent, the scrubber liquor is neutralized and disposed or sold.¹⁷ (See Section 4.1.1.1.3 for a more detailed discussion of waste disposal.) Possible methods of determining the scrubbing liquor changeout point include (1) using liquid level indicators, (2) using specific gravity detectors, and (3) measuring the amount of EO charged to the sterilizer. Reaction towers have been installed for chambers ranging from 1.4 m³ (50 ft³) to 45 m³ (1,600 ft³).^{18,19} Seven of the 188 commercial sterilization facilities represented in EPA's data base use reaction towers to control EO emissions from sterilizer vents. The sterilizers at these seven facilities range in volume from 4 m³ (140 ft³) to 27 m³ (960 ft³). Annual ethylene oxide use at these seven facilities ranges from 2.1 Mg (5,000 lb) to 49 Mg (110,000 lb).^{2,3,5}

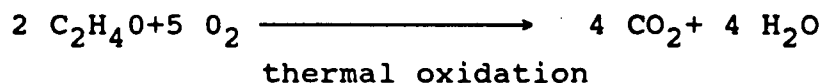
Manufacturers of reaction/detoxification towers claim 99+ percent EO removal efficiency by weight.^{18,20} Third-party laboratory test results indicate that EO emission reductions greater than 99.8 percent can be achieved with reaction towers.¹⁹ However, a detailed review of the available test data indicates that 99.0 percent is the highest EO removal efficiency that can be achieved by acid hydrolysis techniques on a continuous basis.¹⁶

4.1.1.1.3 Waste disposal. The spent liquor from acid hydrolysis of EO is typically 40 to 60 weight percent ethylene glycol and has a pH of 0.5 to 2.0. Because of the low pH, the solution is considered a hazardous waste and thus, requires special handling procedures for shipping. However, the spent liquor can easily be neutralized with sodium hydroxide (caustic) prior to disposal. Two recovery companies have been identified that are willing to purchase the aqueous ethylene glycol

solution.^{21,22} Both of these companies require that sodium hydroxide be used for neutralization and will pick up the solution at the sterilization facility. A third recovery company will accept the spent scrubbing solution on a no cost/no payment basis, except for shipping charges.²³ Neutralized scrubbing solution may also be disposed to a landfill or incinerator.

4.1.1.2 Oxidation. Two methods of oxidizing EO are (1) thermal oxidation with flares and (2) catalytic oxidation with a solid-phase catalyst.

4.1.1.2.1 Thermal oxidation. Ethylene oxide, which has a high heating value, a relatively low ignition temperature, and a very wide range of mixtures combustible in air (see Table 3-4), can be easily and efficiently destroyed by thermal oxidation using flares. Thermal oxidation of EO produces carbon dioxide and water as follows:

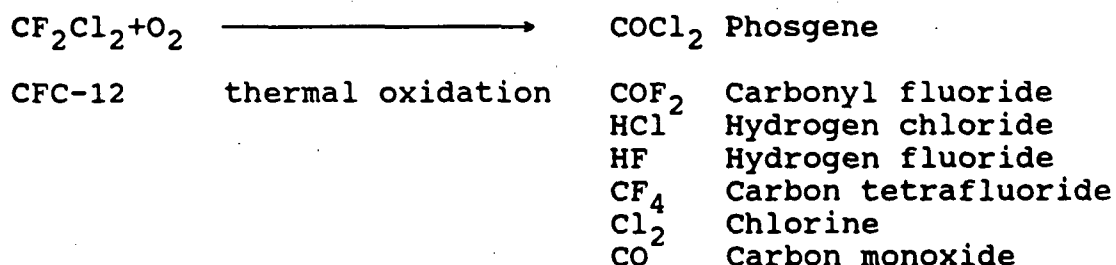


Three of the 188 commercial sterilization facilities represented in the EPA data base reported using flares to control EO emissions when pure EO was used as a sterilant gas.^{2,5} One of these facilities has one 76.7-m³ (2,710-ft³) chamber and uses 26 Mg (57,000 lb) of EO per year. Another facility has three chambers ranging in size from 75.2 to 76.9 m³ (2,655 to 2,715 ft³) and one smaller 1.7-m³ (60-ft³) chamber; this facility uses 89 Mg/yr (197,000 lb/yr) of EO.² The third facility has one 11-m³ (400-ft³) chamber and uses 25 Mg/yr (54,000 lb/yr) of EO.⁵ Because of difficulties with sustaining combustion, commercially available flares are not applicable for facilities emitting only small amounts of EO.

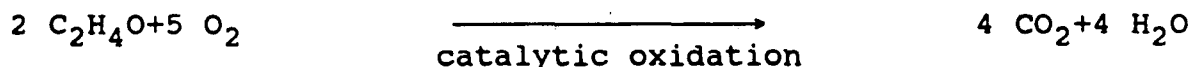
A manufacturer of flare burners for the control of EO emissions claims greater than 99-percent control efficiency for pure EO, but no data were provided to substantiate this claim.²⁴ The EPA's position is that flares operated within specified

conditions of waste gas heat content and flare exit velocity will achieve at least 98-percent destruction efficiency.²⁵

Flares can also be used with EO/CO₂ sterilant gas mixtures (e.g., 10/90) but are not designed for use with EO/CFC-12 mixtures (e.g., 12/88).^{24,26} The EPA has not in the past and does not now recommend the use of flares to control emission streams containing halogenated compounds (e.g., CFC-12) because corrosive or toxic byproducts may form. As shown below, thermal oxidation of CFC-12 may produce the following corrosive or toxic byproducts at the high temperatures (400° to 800°C [800° to 1500°F]) associated with the use of flares:



4.1.1.2.2 Catalytic oxidation. Catalytic oxidation of EO occurs in the presence of a solid-phase catalyst as follows:



This control technique is applicable to pure EO, EO/CO₂ mixtures, and EO/CFC-12 mixtures. The CFC-12 does not react at the temperatures (150° to 180°C [300° to 350°F]) that occur during catalytic oxidation, and, therefore, the toxic CFC byproducts that result from the higher temperatures associated with thermal oxidation are not produced. During an EPA-sponsored test of a catalytic oxidation unit, no CFC decomposition byproducts were detected; the detection limit was 200 parts per billion (ppb) for the analyte chloride ion. The maximum operating temperature of the unit during testing was 155°C (311°F).²⁷

A schematic of a catalytic oxidizer is shown in Figure 4-3. The spent sterilizer gas is first mixed with a large volume of air to reduce the control device inlet EO concentration to 5,000 parts per million by volume (ppmv) or less. This dilution

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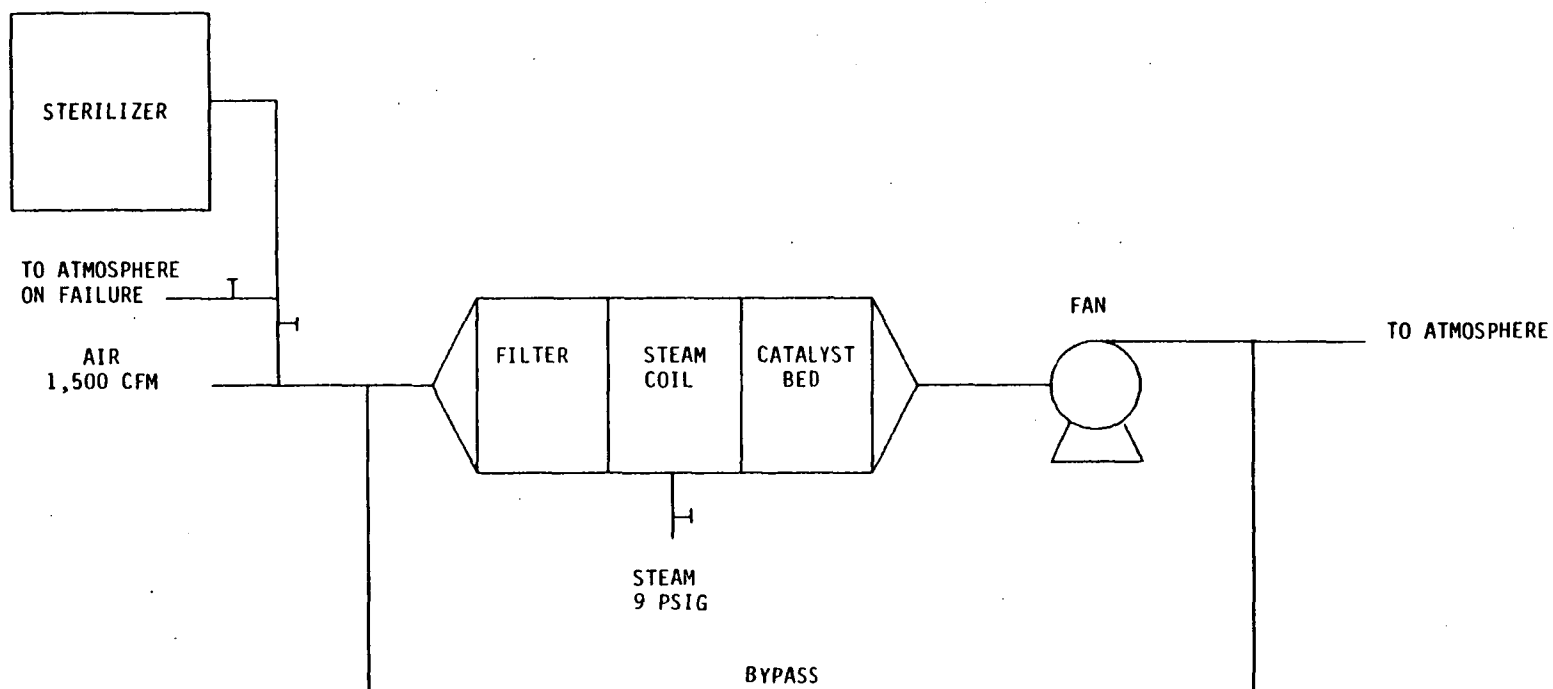


Figure 4-3. Catalytic oxidation system.

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prevents excessive catalyst bed temperatures (which can damage the catalyst) from occurring during the oxidation of EO. The gas stream passes through a filter for dust removal and then is preheated to the reaction temperature with steam or electricity. The gas then enters the catalyst bed(s), where the EO is oxidized. Part of the exiting gas stream may be recycled for heat recovery before being vented to the atmosphere. One manufacturer also sells a catalytic oxidizer that uses excess catalyst, instead of diluent air, to absorb the heat of oxidation.²⁸ Because of cost considerations, the excess-catalyst system has been used, thus far, only for chambers less than 1 m^3 [40 ft^3] in volume.²⁸

Two of the 188 commercial sterilization facilities represented in the EPA data base reported the use of a catalytic oxidizer to control EO emissions from the chamber vent.^{2,4} One facility has one 4-m^3 (130-ft^3) chamber and uses 0.5 Mg/yr ($1,000 \text{ lb/yr}$) of EO in an EO/ CO_2 sterilant-gas mixture.² The other facility has an 18-m^3 (600-ft^3) sterilizer and uses 7 Mg ($15,000 \text{ lb}$) of EO annually; the EO concentration to the control unit at this facility is regulated by throttles.⁴

Because catalytic oxidation is applicable to the control of low EO concentrations, facilities can manifold other EO emission sources (e.g., aeration chambers or rooms, sterilizer hood and door vent, and the gas cylinder room) to the control device. In addition, if the catalytic oxidizer requires diluent air, these low-concentration emission sources can provide part or all of the necessary diluent.

Manufacturers of catalytic oxidation units claim EO destruction efficiencies greater than 99.9 percent.^{29,30} Third-party testing and an EPA-sponsored test support these claims for small ($<0.85 \text{ m}^3$ [$<30 \text{ ft}^3$]) sterilizers.^{27,29}

4.1.1.3 Condensation/Reclamation Systems. Recovery of sterilant gas mixtures is possible using a reclamation system. The sterilant gas mixtures will condense under conditions of

reduced temperature and increased pressure, but precautions are necessary to avoid explosions.

Figure 4-4 is a schematic of a condensation/reclamation system for a 12/88 sterilant-gas mixture. (See Table 3-4 for physical and chemical properties of CFC-12.) After each sterilization cycle, the 12/88 gas is withdrawn and passed through one of the two desiccant beds next to the chamber. (One of the desiccant beds is regenerated while the other is in use.) The dried 12/88 gas then passes to a compressor where it is compressed to 345 kilopascals (65 psia) to improve condensation efficiency.³¹ The compressed gas is piped to a separate explosion-proof room, where it passes through a pressurized condenser that is chilled by ethylene glycol to about -18°C (0°F).³¹ The liquid 12/88 mixture is collected in a pressurized, chilled holding tank. The noncondensed gas is recirculated to the chamber and back through the condenser. The liquid collected in the holding tank is transferred to a pressurized reblending tank where the liquid is mixed and its composition determined by infrared analysis. The liquid is then adjusted to the 12/88 (weight percent) ratio by adding the necessary amount of EO or CFC-12. When the correct ratio is obtained, the liquid is transferred to a pressurized storage tank in the chamber room.³¹

Although the reclamation cycle could be continued indefinitely, the amount of EO recovered declines to the point where it is not cost effective to continue the reclamation cycle after about three passes through the system (i.e., typically 60 to 90 minutes). The majority of the EO (80 to 85 percent) is recovered during this time. Also, increasing the reclamation time would require that products spend additional time in the sterilizer and could affect the plant's operating schedule. However, even if the reclamation time was increased, this system is not designed for low EO concentrations. Therefore, if this type of control system is used, add-on controls (e.g., catalytic oxidation or a small scrubber) need to be considered for the EO remaining in the chamber after the reclamation cycle is complete.

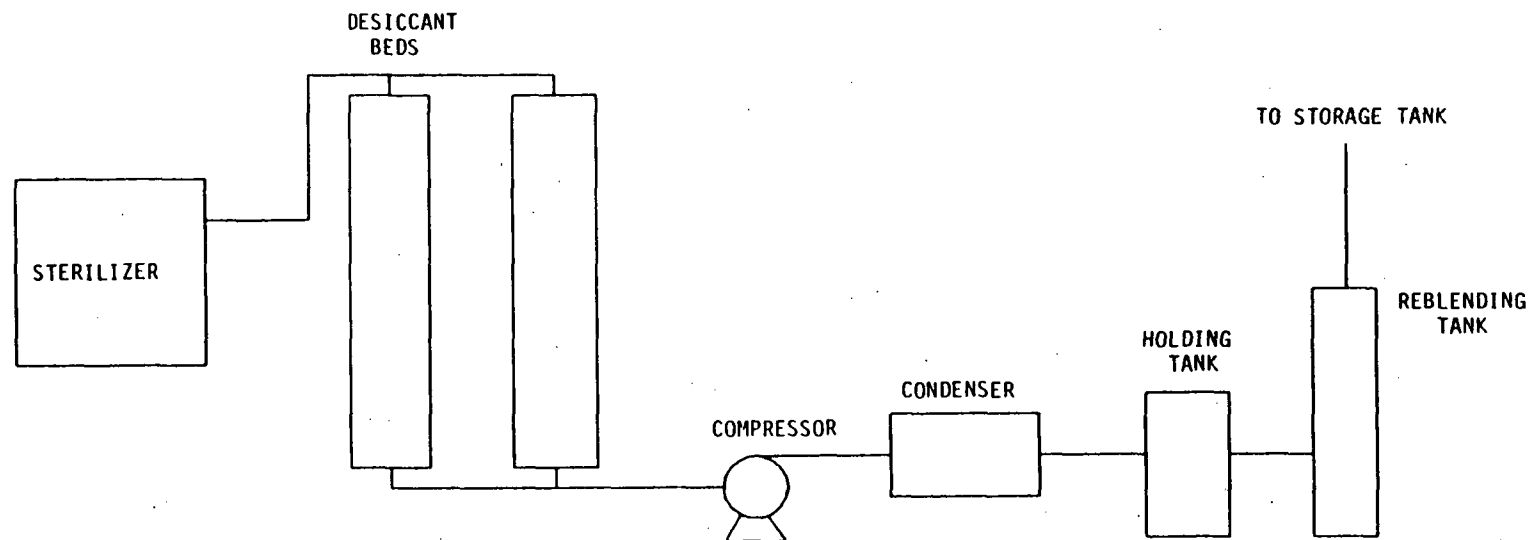


Figure 4-4. Condensation/reclamation system.

Six of the 188 commercial sterilization facilities represented in the EPA data base reported the use of condensation/reclamation systems; one of these facilities reported an 83-percent EO recovery efficiency, four reported 80 percent, and one reported 50 percent.^{2,3,5} These six facilities recover EO/CO₂ and EO/CFC-12 sterilant gases. Five of these facilities use over 23 Mg/yr (50,000 lb/yr) of EO.^{2,3,5} The sixth facility uses just over 6.8 Mg/yr (15,000 lb/yr).^{2,3} The chamber sizes range from 5 to 45 m³ (190 to 1,580 ft³) at these six facilities.^{2,3,5}

The condensation/reclamation systems currently available are designed for the high volumetric flow rates of larger, industrial-sized chambers. The systems are not technically or economically feasible for use with smaller chambers or at facilities that use small amounts of EO.

4.1.1.4 Gas/Solid Reactor. A fourth control technique to control vent emissions is a dry, solid-phase system that chemically converts EO and then binds the product to the solid packing.¹ This system is generally paired with an acid water scrubber. The system operates at room temperature. There are no liquid waste streams produced; the solid waste is returned to the vendor for recycling.^{32,33} Although the gas/solid reactor can handle high EO concentrations (i.e., >100,000 ppmv) for brief periods of time, it is designed for low concentrations such as the exhaust from an acid-water scrubber. The manufacturer of this device markets a two-stage control system, which consists of an acid-water scrubber and the gas/solid reactor. (The company also sells the stages separately.) The majority of the EO is removed by the scrubber, which is specifically designed for small sterilizers (<2 m³ [70 ft³]). The gas/solid reactor removes the residual EO exiting the scrubber and, because it is designed for low EO concentrations, can also be manifolded to other emission sources (e.g., aeration chambers, sterilizer hood and door, and gas cylinder storage room).

The manufacturer of this system claims greater than 99.9 percent efficiency for the gas/solid reactor.¹ However,

this efficiency is based on a test performed with an inlet EO concentration of 140,000 ppmv, which is much higher than the concentration of the scrubber outlet stream. In another test, no EO was detected (with a lower detection limit of 0.1 ppmv) in the gas/solid reactor outlet stream when the inlet stream (i.e., scrubber outlet stream) was 2 ppmv EO.³² Because of the inherent problems associated with measuring low EO concentrations, the actual efficiency of the system under normal operating conditions presently cannot be determined. (See Section 4.1.3 for a more detailed discussion of measuring low EO concentrations.) However, the maximum removal efficiency that the gas/solid reactor can achieve on a continuous basis is assumed to be 99.0 percent.

4.1.2 Sterilization Chamber Vacuum Pump Drain Emissions

Ethylene oxide drain emissions result from the use of vacuum pumps that use once-through water as the working fluid. Ethylene oxide is infinitely soluble in water, and, therefore, a portion of the EO evacuated from the chamber enters the drain with the vacuum pump water (see Figure 4-5a). The EO that enters the drain with the vacuum pump water is subsequently released uncontrolled from the air break in the drain line, sewer lines, or the waste water treatment plant.⁶⁻⁸

The EO drain emissions can be eliminated by replacing the existing once-through vacuum pump with a closed-loop (recirculating-fluid) vacuum pump. The recirculating fluid (sealant) can be water, oil, or ethylene glycol.³⁴ In this closed-loop system, the water or liquid from the liquid-gas separator is cooled in a heat exchanger and recirculated through the vacuum pump (see Figure 4-5b). Because ethylene oxide is not soluble in oil or ethylene glycol and will off-gas from water as it is recirculated, nearly all of the EO will be emitted through the liquid-gas separator (chamber) vent. (Techniques for control of chamber vent emissions are discussed above.) In addition, mechanical seals are used to eliminate leakage (and, thus, any EO emissions) from the pump.³⁵

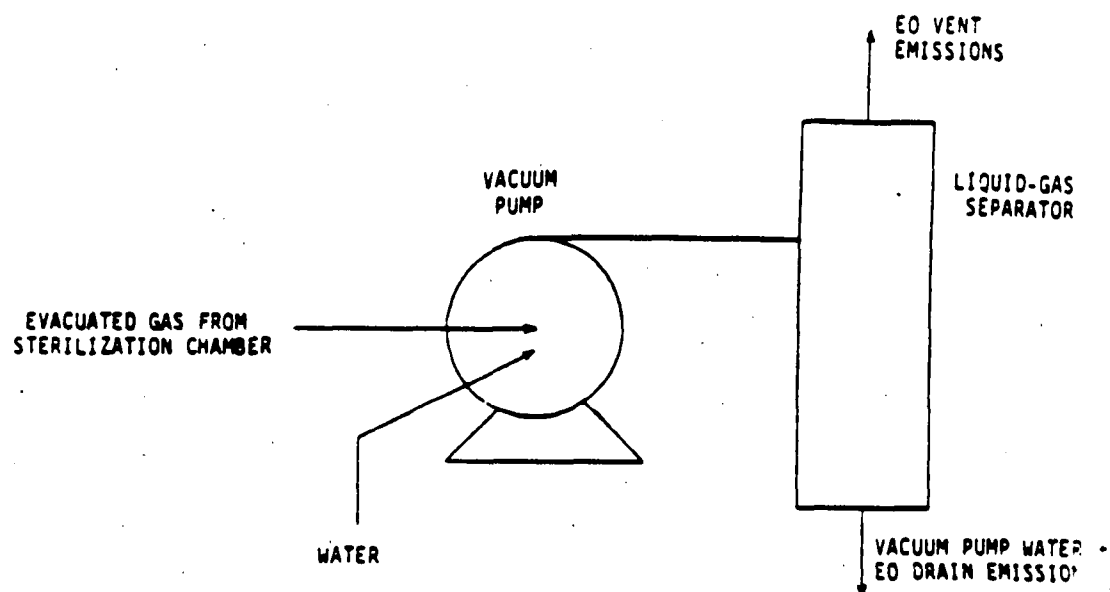


Figure 4-5a. Once-through liquid-ring vacuum pump.

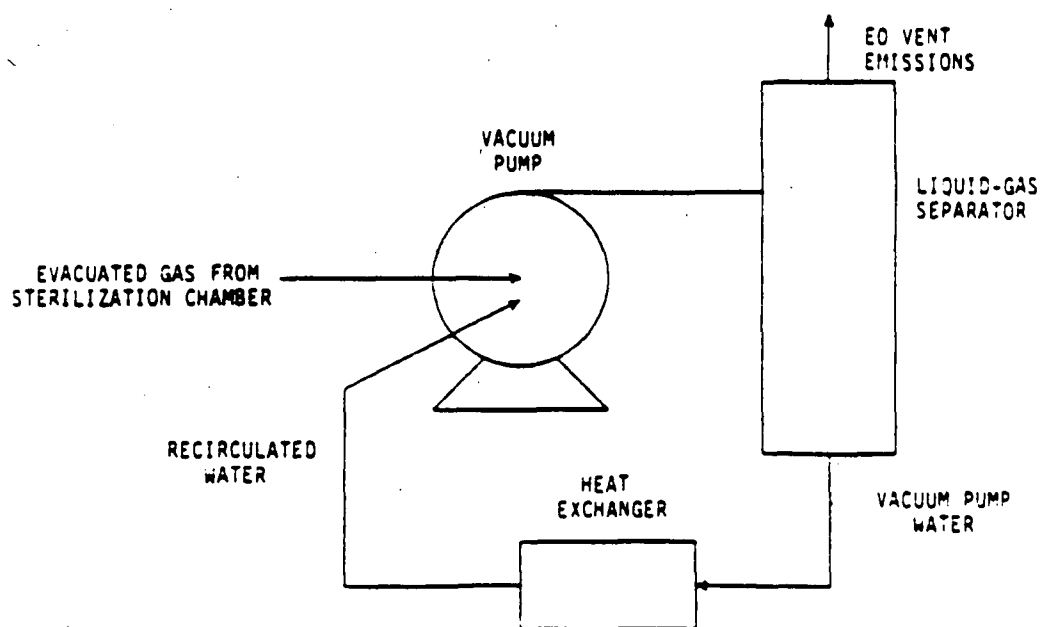


Figure 4-5b. Recirculating liquid-ring vacuum pump.

Because the sterilization cycle operates under humid conditions, some water will be condensed in the liquid-gas separator and, thus, mix with the liquid sealant in the pump. An overflow collection tank is used to maintain a constant amount of sealant recirculating in the pump.³⁵ If ethylene glycol is used as the sealant, the contaminated glycol will eventually need to be disposed and replaced with a fresh charge.³⁵ However, if oil is used as the sealant, the condensed water can be drained off the bottom with minimal oil loss because of the immiscibility of oil and water.³⁴

4.1.3 Chamber Exhaust Emissions

Some facilities, in an effort to meet the EO permissible worker exposure level set by the Occupational Safety and Health Administration (OSHA) (see Section 3.5), have installed chamber exhaust vents on sterilizers. The purpose of the exhaust is to quickly dilute EO concentrations in the sterilizer chamber void space and thereby prevent exceedances of exposure limits for workers. Other facilities have installed hoods above the chamber door to reduce worker exposure. At present, there are no data on controlled chamber exhaust emissions in the commercial sterilization data base. As with aeration rooms (see Section 4.1.4.1 for a more detailed discussion), the low-concentration, high-flow-rate exhaust streams of chamber exhausts limit the feasibility and efficiency of add-on controls (particularly thermal oxidation and condensation/reclamation), and the lower detection limit of most analytical methods may make it impossible to determine the efficiency of the control devices at the concentrations typical of the chamber exhaust stream. The same control techniques that are applicable to the control of aeration room emissions (i.e., catalytic oxidation units and gas/solid reactors) may also be applicable to chamber exhaust emissions. In addition, acid/water scrubbers may also be feasible.

The typical chamber exhaust provides a flow rate of $84 \text{ m}^3/\text{min}$ ($3,000 \text{ ft}^3/\text{min}$), and the EO concentration in the void volume as the sterilizer door is opened is estimated to be 500 to 15,000 ppmv, depending on sterilizer operating parameters. As

the diluent air enters the chamber, the EO concentration rapidly decreases to below the 1 ppmv OSHA limit. Some EO may evolve from the product during the chamber exhaust cycle, but this amount is negligible when compared to the EO concentration in the void volume.

4.1.3.1 Acid-Water Scrubber. As discussed in Section 4.1.1.1, acid-water scrubbers are commonly used to control sterilizer vent emissions, which have low to moderate flow rates (0.7 to $14 \text{ m}^3/\text{min}$ [25 to 500 ft^3]) and potentially high EO concentrations ($400,000 \text{ ppm}$).²⁰ Under these conditions, acid-water scrubbers can achieve EO removal efficiencies of 99 percent or greater.⁶ While it is technically feasible to control the higher-flow-rate, lower-concentration emissions from the chamber exhaust, the EO removal efficiency of the scrubber may be reduced. The potential decrease in efficiency would be due to decreased residence times of EO in the scrubber and because there would be less EO to react in the scrubbing liquor. Because an acid-water scrubber has never been demonstrated to control chamber exhaust emissions, the control efficiency of the unit under these conditions is unknown.

4.1.3.2 Catalytic Oxidation System. As discussed in Section 4.1.1.2.2, the inlet EO concentration for excess-air catalytic oxidizers is typically reduced to 5,000 ppmv or less, which means that use of this control device could be feasible with chamber exhaust streams. Catalytic oxidation units are also commercially available to handle flow rates from chamber exhausts.^{37,38} While no catalytic oxidizers are known to have been installed to control chamber exhaust emissions, units have been installed to control aeration room emissions. As discussed in Section 4.1.4.1, the control efficiency of these units has not been adequately demonstrated.

4.1.3.3 Gas/Solid Reactor. Like the catalytic oxidizers, the gas/solid reactor is designed for low concentration ($<100 \text{ ppm}$) inlet streams.³³ As discussed in Section 4.1.4.1, gas/solid reactors are being used for flow rates up to $42 \text{ m}^3/\text{min}$ ($1,500 \text{ ft}^3/\text{min}$), and systems can be sized to accommodate larger

flow rates.³⁹ However, the control efficiency of these units with low EO concentrations has not been adequately determined.

4.1.4 Aeration Room Vent Emissions

4.1.4.1 Aeration Rooms. Most commercial sterilization facilities aerate the sterile products in large, warehouse-type aeration rooms that are typically 280 to 2,800 m³ (10,000 to 100,000 ft³) in volume but may be larger than 14,000 m³ (500,000 ft³).⁴ The ventilation rates are, generally, in the range of 112 to 560 m³/min (4,000 to 20,000 ft³/min) but may be as high as 1,680 m³/min (60,000 ft³/min).⁴ These large flow rates are necessary to maintain a low EO concentration in the room to comply with OSHA standards (see Section 3.5). Data from a cross-sectional survey (44 facilities) of the 188 commercial sterilization facilities represented in EPA's data base indicated an average 8-hour, time-weighted average (TWA) EO concentration of 2.5 to 3 ppmv in aeration rooms.⁴

Two issues of concern regarding the control of aeration room emissions are: (1) most EO emission control devices are impracticable for the low-concentration, high-flow-rate exhaust streams from aeration rooms; and (2) the lower detection limit of most analytical methods may make it impossible to determine the true control efficiency of the low EO concentrations (less than 1 ppmv) found in most aeration rooms. Hydrolysis, thermal oxidation, and condensation/reclamation presently have not been demonstrated to be practicable control techniques for low-concentration, high-flow-rate gas streams. However, catalytic oxidation and the gas/solid reactor system have the potential to control aeration room emissions. Catalytic oxidation units are commercially available to handle flow rates from less than 1 m³/min (40 ft³/min) to approximately 340 m³/min (12,000 ft³/min).^{37,38} The catalytic oxidizers are modular, and systems can be designed to handle higher flow rates; however, the increased size of the system for high flow rates can restrict its practical use. Gas/solid reactors are being used for flow rates up to 42 m³/min (1,500 ft³/min), and systems can be designed to

handle any flow rate; however, as with catalytic oxidation, the system size can become impractical.³⁹

The manufacturers of catalytic oxidizers and gas/solid reactors claim EO destruction efficiencies greater than 99.9 percent and offer the results of third-party tests to support these claims.^{32,40,41} However, test data are not available on the efficiencies of the control units operating under conditions that are typical of aeration room exhaust streams (i.e., low concentrations and high flow rates).

Generally, the control units are tested by sending the control device a stream of EO with a much higher concentration (e.g., 100 to 140,000 ppmv) than that associated with normal operating conditions.^{32,40,41} The results of these tests are the efficiencies reported by the manufacturers. However, these test results may be misleading because: (1) it has not been demonstrated whether the control units perform at the same efficiencies under normal operating conditions (i.e., very low inlet concentrations) as during test conditions (i.e., controlled flow, high concentration); (2) EPA has not conducted its own emission test program to verify the efficiency of control devices with aeration room emissions; and (3) EPA has not yet developed or approved a test reference method that is applicable to the evaluation of the efficiencies of these control devices with aeration room emissions.

The lower detection limits of most analytical procedures that are used to measure EO concentrations are approximately 0.5 ppmv to 1 ppmv, which is equal to or greater than the EO concentrations in many aeration rooms. Although one testing laboratory reportedly used a method with a detection limit less than 0.1 ppmv, the test data have not been verified by EPA, and it is unknown whether this method can be applied to high flow rates. (The flow rate tested was 14 m³/min [500 ft³/min].)⁴¹ Also, because of the reactivity of EO, the validity of detection limits below 1 ppmv, and particularly below 0.5 ppmv, is questionable.⁴² Because the detection limits of the analytical methods (in ppmv) are so close to the room concentrations,

testing under normal operating conditions may yield an efficiency that can only be calculated to be equal to 50 percent or less.

Three possible techniques for reducing EO emissions from aeration rooms are to (1) recirculate the air from the aeration room control device to the aeration room, (2) replace the warehouse-type aeration rooms with smaller, heated aeration chambers, or (3) modify the evacuation and air wash phase of the sterilization cycle. The first two techniques increase the EO concentration in the aeration room and lower the flow rate, which makes both control of the emissions and testing of the control efficiency more practical. The third alternative lowers the EO emissions from the aeration room by decreasing the residual EO in the product prior to aeration. These techniques are discussed in more detail below.

The first alternative refers to routing the aeration room air through an emission control device and back to the aeration room. A small amount of makeup air is added to the control device exit stream to regulate the room temperature. This practice increases the room temperature and, therefore, increases the diffusion rate of EO from the product, producing a higher EO concentration in the room. (Worker exposure and compliance with the OSHA standards will need to be considered if frequent worker access to the room is required.) Catalytic oxidation and the gas/solid reactor are more applicable to gas streams having increased EO concentrations and decreased flow rates associated with this process than to typical aeration room emissions. In addition, increasing the room temperature reduces the energy costs of preheating the inlet stream to the catalytic oxidizer. Hydrolysis, thermal oxidation, and condensation/reclamation are not applicable control techniques because the EO concentrations are too low (<20 ppmv) for these techniques to be practicable. Because the room air is recirculated and not vented to the atmosphere, this technique eliminates practically all aeration room emissions; only a small amount of the emissions from the control device are vented to allow fresh makeup air to enter the room. This practice of recirculating the aeration room air is

used by 2 of the 188 commercial sterilization facilities represented in the EPA data base.³ The aeration rooms at these two commercial sterilization facilities are each approximately 140 m³ (5,000 ft³) in volume.⁴ These two facilities manufacture synthetic rubber products, which retain a large amount of residual EO and, therefore, require a longer aeration period than the majority of products that are sterilized with EO. The facilities installed the recirculating system to decrease the aeration time and the residual EO concentrations in the products.⁴¹ A catalytic oxidation system is used to control the EO emissions at these facilities and to provide hot air to heat the room.⁴³

Another alternative is to replace the large, warehouse-type aeration rooms with smaller (70 m³ [2,500 ft³] or less), heated aeration chambers and control the emissions from the chamber. In this process, instead of storing the sterile products in a warehouse and aerating at normal room temperatures, the products are aerated in heated (>43°C [110°F]), insulated chambers. The emissions from these units can be controlled by catalytic oxidation or the gas/solid reactor system. Emissions from the control device can be recirculated to the aeration chamber or vented to the atmosphere. The aeration chambers can be filled approximately 40 to 75 percent full and still allow sufficient air space for off-gassing.^{28,44} The aeration chamber is heated with either supplemental heat or hot air from the control device if catalytic oxidation is used. Several commercial sterilization facilities, particularly contract sterilizers, are aerating at least some of the sterile products in heated, aeration chambers.^{4,38} Structures used for aeration include insulated shipping containers, modified walk-in coolers (which are heated instead of cooled), and manufactured units designed specifically for the heated aeration process.⁴⁵⁻⁴⁷ Most of these facilities have installed these chambers to reduce the aeration time or the residual EO concentration in the products. The heated aeration chambers are similar to the first technique described above (i.e., the practice of recirculating the aeration room air) in

that the EO concentration in the chamber will increase as a result of EO off-gassing from the product due to elevated temperature.

Another strategy for reducing aeration room emissions is to modify the evacuation/air wash phase of the sterilization cycle. Residual EO in the product can be reduced by performing additional sterilization chamber purges. However, this procedure requires that products be held for additional time in the sterilizer and could affect plant operating schedules. The potential reduction in residual EO with evacuation-phase modifications is product dependent. Results from tests performed at one facility that fumigates spices showed an average reduction in residual EO of 26 percent for four different spices following evacuation-phase modifications.¹⁵ Some facilities aerate in the sterilizer, with and without cycle modifications.⁴ Aeration emissions from the sterilizer can be sent to the sterilizer control device. However, the removal efficiencies of the hydrolysis techniques have not been determined for the low inlet concentrations associated with aeration emissions. Also, condensation/reclamation would not be practicable for controlling these low concentrations.

An additional system currently used to control EO emissions from aeration rooms is an acid-impregnated carbon adsorption system. When such a system is used, emissions from an aeration room or aeration cabinet (see Chapter 4.1.4.2) are ducted to the carbon adsorption system which typically consists of approximately 20 acid-treated carbon trays. The carbon in these carbon trays has been treated with a strong acid (e.g., sulfuric acid) and is humidified. The EO in the emissions from the aeration room(s)/cabinet(s) is hydrolyzed to ethylene glycol. Because of its increased affinity for EO, the EO removal efficiency of the acid-impregnated carbon greatly exceeds that of plain carbon. However, the actual removal efficiency for this emissions control device have not yet been determined.⁴⁸

4.1.4.2 Aeration Cabinets. Some commercial sterilization facilities use aeration cabinets instead of aeration rooms.

These cabinets are similar in appearance and size ($<1 \text{ m}^3$ [40 ft^3]) to the sterilization chambers used at hospitals. However, the flow rate from the cabinet is much lower than that from aeration rooms. Therefore, catalytic oxidation and the gas/solid reactor are applicable to the control of EO emissions from aeration cabinets. Several small commercial sterilization facilities use catalytic oxidation or the gas/solid reactor system to control aeration cabinet emissions, and at least one commercial sterilization facility uses an acid-water scrubber to control these emissions.^{4,37,49} However, as stated in Section 4.1.3.1, the control efficiencies of these techniques have not been determined for the low concentrations from aeration processes.

4.2 OTHER STERILIZATION PROCESSES

There are no demonstrated EO emission control devices for single-item sterilization processes or for portable fumigation units, including beehive fumigators. The problems associated with controlling EO emissions from these sources are discussed below.

4.2.1 Single-Item Sterilization

Single-item sterilization systems do not use a chamber evacuated with a vacuum pump. (See Section 3.2.2 for a description of single-item sterilization.) Instead, the EO is allowed to diffuse from products while they are inside an aeration room or cabinet. The EO from facilities using single-item sterilization systems is, therefore, emitted from one major source, the aeration room/cabinet vent. Because there is no evacuation phase, the EO concentration in the gas stream from single-item sterilization systems is higher than the concentration of EO in aeration rooms. However, the concentration is sufficiently low such that catalytic oxidation or the gas/solid reactor system may be viable control options.

4.2.2 Fumigation with Portable Units

Because of problems with transporting an emission control device, it is not practical to control EO emissions from the portable units operated by State departments of agriculture to

fumigate beehives. However, one State Department of Agriculture is working on the development of an acid-water scrubber for portable fumigation units.³

4.3 ALTERNATIVES TO EO STERILIZATION

In some cases, radiation sterilization can replace EO sterilization. Radiation sterilization is used for about half of the products sterilized in the United States.⁵⁰ However, not all products can be sterilized with radiation; plastics can become broken, discolored, or rendered malodorous, and Teflon® and acetyl delrin are damaged by radiation.^{50,51} According to industry representatives, most of the commonly used plastics have been or are in the process of being reformulated to withstand radiation.^{52,53} Therefore, the potential use of this alternative may increase.

There are several chemical alternatives to EO sterilization (e.g., chlorine dioxide, gas plasma, hydrogen peroxide, and ozone). However, these chemicals do not necessarily offer environmental improvements over EO. Other alternatives include X-ray sterilization (a new, developing technology), deep freezing (museum and spice industry), and increased use of disposable medical items in hospitals. However, none of these alternatives can replace the use of EO for all applications, and they may have adverse environmental impacts as well. For example, the increased use of disposables may conflict with a pollution prevention program. Additionally, there may be significant health effects if these alternatives produce less-effective sterilants.⁵⁴

4.4 RETROFIT CONSIDERATIONS

All of the control devices discussed above can be retrofitted to existing EO bulk sterilization chambers. However, the use of flares in urban areas is prohibited because of safety hazards. There are no retrofit problems associated with the replacement of once-through vacuum pumps with closed-loop recirculating vacuum pumps for control of drain emissions.

4.5 IMPACTS OF CFC REGULATION ON EO EMISSION CONTROLS

Federal regulations for stratospheric ozone-depleting chlorofluorocarbons (CFC's) have been developed under EPA's Stratospheric Ozone Protection Program (SOPP). The use of CFC's in sterilant gases is one of the source categories subject to the CFC regulation. The most popular sterilant gas mixture, 12/88, contains 88 percent by weight CFC-12, which is an ozone-depleting CFC. Seventy-five percent of the 188 commercial sterilization facilities represented in the EPA data base use 12/88 at least part of the time.^{2,3,5} The requirements of a CFC regulation would not change the ability of a sterilization facility to control EO emissions. The explosion-proof condensation/reclamation system discussed above recovers CFC-12 emissions in addition to EO emissions. However, if this control device is used, add-on controls (e.g., catalytic oxidation or a small scrubber) need to be considered for the EO remaining in the chamber after the reclamation cycle is complete. Also, a dedicated CFC-12 condensation/reclamation system that follows the acid-water scrubbing of EO to ethylene glycol would not have to be explosion-proof.⁵⁵ Some facilities may switch to sterilant gases that do not contain CFC-12 (such as 10/90 and pure EO), in which case the EO control techniques discussed above would still be applicable.

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5.0 REGULATORY ALTERNATIVES

5.1 INTRODUCTION

The purpose of this chapter is to present the regulatory alternatives developed by EPA. These regulatory alternatives represent the various courses of action that EPA could take in controlling ethylene oxide emissions from commercial sterilization facilities. The environmental, cost, and economic impacts associated with the application of these alternatives to this source category are presented in subsequent chapters. The EPA has developed a facility-specific data base for this source category; the impacts of the regulatory alternatives are based on actual facility data.

Data in the EPA commercial sterilization (CS) data base include facility-specific information from 196 facilities. This information was obtained through a November 1985 Health Industry Manufacturers' Association (HIMA) survey of medical equipment suppliers and a July 1986 Section 114 information collection request submitted to miscellaneous sterilizers and fumigators. Additional information that was used to update the 1986 EPA CS data base was obtained from two subsequent Section 114 information requests (July 1988 and July 1989). Facilities using single-item sterilization (Sterijet®) units and beehive fumigators used by State agriculture departments were not included in the regulatory analyses because there are no demonstrated control technologies for facilities using these sterilization processes (see Section 4.2). Therefore, 188 facilities that operate a total of 404 sterilization chambers are included in the regulatory alternatives analyses. These

facilities are grouped by Standard Industrial Classification (SIC) code into the following categories:

1. Medical equipment suppliers;
2. Pharmaceuticals;
3. Other health-related industries;
4. Spice manufacturers;
5. Contract sterilizers;
6. Libraries, museums, and archives; and
7. Laboratories (research, testing, and animal breeding).

The data base includes information on the number of chambers, chamber size, sterilant gas type, total annual sterilant gas throughput, annual EO use, and levels of emission control.

5.2 REGULATORY ALTERNATIVES

Table 5-1 presents the regulatory alternatives EPA developed to evaluate the environmental and cost impacts of potential emissions controls on commercial sterilization facilities. The regulatory alternatives represent incremental increases in the use of control devices and decreases in the EO use cutoffs that are applicable to the emissions sources. The control devices examined exhibited control efficiencies consistent with those comprising the (MACT) floor. In other words, these devices provide an emission reduction that is at least as stringent as the average emission limitation achieved by the best performing 12 percent of the existing sources. The cutoff levels are based on a facility's total annual EO use. Any facility with an annual EO use rate greater than or equal to the particular cutoff level would be subject to regulation. The analysis of emissions control versus the impacts of control yielded a nonclustered, continuous curve from which clear regulatory cutoffs were not readily determined. However, the trend of the data indicates that lower ethylene oxide annual use rates resulted in higher costs. The cutoff levels presented in Table 5-1 reflect this trend. Sterilization chamber size was also considered as a basis for regulatory alternatives. However, although the sterilization

TABLE 5-1. REGULATORY ALTERNATIVES

Regulatory Alternative	Emission source						Total nationwide emission reduction
	Sterilizer vent		Aeration room		Chamber exhaust		
	Cutoff, kg/yr (lb/yr)	Control device efficiency, percent	Cutoff, kg/yr (lb/yr)	Efficiency of control device, percent	Cutoff, kg Mg/yr (lb/yr)	Efficiency of control device, percent	
A	11 (25)	99	11 (25)	99	11 (25)	98	99
B	270 (600)	99	18,160 (40,000)	99	270 (600)	98	97
C	270 (600)	99	18,160 (40,000)	99	Status quo ^a	N/A ^b	94
D	270 (600)	99	No controls	N/A ^b	Status quo ^a	N/A ^b	91
E	900 (2,000)	99	No controls	N/A ^b	Status quo ^a	N/A ^b	90

^aStatus quo means that baseline chamber exhaust emissions are not exceeded.

^bN/A = Not applicable.

5-3

chamber size is related to the quantity of EO used, actual EO use is a more direct measure of emissions.

Regarding the 900 kilograms per year (kg/yr) (2,000 pounds per year [lb/yr]) EO use cutoff for sterilizer vent and chamber exhaust emissions controls, no plants in the CS data base using less than 900 kg/yr (2,000 lb/yr) of EO have controlled emissions from sterilizer vents or chamber exhausts. Regarding the 18,160 kg/yr (40,000 lb/yr) EO use cutoff for aeration room emissions control, none of the existing sources presently control emissions from facilities using less than 18,160 kg/yr (40,000 lb/yr) of EO. Additionally, risk modeling data indicated that emissions from sources above these cutoffs would pose a more significant threat to human health and the environment. Also, cost estimates show that the cost impacts would be unreasonably high for sources below these cutoffs.

Estimates for emission rates and the cost of regulatory compliance are based on the following control technologies: EO emissions from the sterilizer vent would be controlled by an acid-water scrubber, and vacuum-pump drain emissions would be controlled by replacing the once-through, water-sealed, vacuum pump with a vacuum pump that has a closed-loop recirculation system. All EO entering the vacuum pump would be routed to the control device through the sterilizer vent rather than being split between the vent and drain, thus eliminating EO emissions from the drain. Aeration room emissions would be controlled by either a catalytic oxidizer or solid-bed reactor. The same controls as the aeration room would apply to chamber exhaust emissions.

The alternatives are presented in decreasing order of stringency. Regulatory Alternative A represents the maximum nationwide level of control. At this level, an estimated 99 percent of ethylene oxide emissions from commercial sterilization operations would be captured and controlled. All facilities in the data base would be subject to the control requirements because there are no facilities in the EPA data base that use less than 11 kg (25 lb) of EO per year. Regulatory

Alternative B has less stringent maximum EO use cutoffs. Under Regulatory Alternative C, a cap on chamber exhaust emissions limiting emissions to baseline emission levels would be required; additional controls are assumed necessary to maintain the baseline level. Under Regulatory Alternatives D and E, the only emission source to be controlled is the main sterilizer vent. Regulatory Alternative E represents the MACT floor for existing sources; at least 12 percent of the best performing existing sources already apply a 99-percent efficient control device to control sterilizer vent emissions.

It is important to note that while the efficiency of acid-water scrubbers (at least 99-percent) is widely accepted, the efficiencies assumed for the controls for aeration rooms and chamber exhaust vents are not well supported. For purposes of the analyses in this document, 99 and 98 percent were selected for the aeration room and chamber exhaust vent control device efficiencies, respectively. However, actual control efficiencies may be lower given the high-flow, low concentration emissions streams that are typical of these emissions sources.

6.0 ENVIRONMENTAL IMPACTS

This chapter presents estimated primary and secondary impacts on air, water, solid waste, and energy for each of the regulatory alternatives discussed in Chapter 5. Both beneficial and adverse impacts, as well as potential emission reductions, are assessed for the 188 facilities represented in EPA's 1989 commercial sterilization (CS) data base. Because no significant growth is expected for this industry, the 5-year impacts are the same as current impacts, and, therefore, only current impacts are presented in this section.^{1,2}

6.1 AIR POLLUTION IMPACTS

6.1.1 Baseline Emissions and Emission Reduction

Based on facility-specific data in the EPA 1989 CS data base, baseline EO emissions and potential emission reductions were calculated for each of the regulatory alternatives described in Section 5.2. The control devices (and their efficiencies) at each emission point considered were respectively: (1) acid-water scrubber for sterilizer vent (99 percent); (2) recirculating-fluid vacuum pump for sterilizer vent drain (100 percent); (3) acid-water scrubber for chamber exhaust (assumed to be 98 percent), and (4) a gas/solid reactor for aeration room vent (99 percent).

The total nationwide estimated potential emission reductions and residual emissions for each of the five regulatory alternatives are presented in Table 6-1.

6.1.2 Secondary Impacts

Secondary air pollutants are those emissions that are not usually associated with an uncontrolled facility but result from the use of pollution control equipment (i.e., the control of one

TABLE 6-1. NATIONWIDE AIR IMPACTS

Regulatory Alternative	Nationwide emission reduction, %	EO emission reduction, Mg/yr (tons/yr)	EO residual emissions, Mg/yr (tons/yr)
A	99	1,061 (1,170)	11 (12)
B	97	1,042 (1,148)	30 (33)
C	94	1,004 (1,107)	68 (75)
D	90	963 (1,062)	109 (120)
E	89	952 (1,049)	120 (132)

Source: U. S. EPA Ethylene Oxide Commercial Sterilization Data Base, 1986, 1988.

pollutant results in the production of another pollutant). Secondary air pollutants are not associated with the use of acid-water scrubbers, recirculating-fluid vacuum pumps, or gas/solid reactors.

6.2 WATER QUALITY IMPACTS

If an acid-water scrubber is used to control EO emissions, there may be water quality impacts, depending on how the spent scrubber solution (predominately ethylene glycol) is disposed. Ethylene glycol is generated when the EO exhaust stream contacts and then reacts with the acid-water solution in the scrubber. When this solution is spent, the scrubber tank must be emptied and a fresh acid-water solution added. Each tank initially holds about 220 gallons (833 liters) of a 10 percent (by volume) aqueous sulfuric acid (H_2SO_4) solution, which is neutralized with 50 percent (by weight) caustic (NaOH) before the tank is drained.³ (See Appendix E Section E.2 [sample calculations for acid-water scrubbers, assumption 3] for a sample calculation of the amount of ethylene glycol solution produced per pound of EO entering the scrubber.) The amount of ethylene glycol solution produced was calculated based on the assumption that the scrubber would be drained after 907 kilograms (kg) (2,000 pounds [lb]) of EO were treated, resulting in a 64 percent (by weight) aqueous solution of ethylene glycol.

Several methods for the final disposal of the ethylene glycol were examined. The ethylene glycol produced by the scrubber can be removed by a waste disposal company, sent to a municipal wastewater treatment plant, or shipped to a recovery plant. Removal of the ethylene glycol by a waste disposal company may not be economically practical for all of the facilities; this disposal method could account for a high percentage of the annual operating costs.³ Sending the ethylene glycol solution to a municipal wastewater treatment plant also would not be feasible for all sterilization facilities. Some municipal treatment facilities restrict the concentration level and amount of ethylene glycol allowed in the discharge to the wastewater treatment plant.³

The final disposal method examined was shipping the ethylene glycol solution to a recovery company. At least three companies accept the ethylene glycol solutions for recovery on a no-credit, no-cost (except for shipping) basis.⁴⁻⁶ Shipment of the ethylene glycol solution to a recovery company is a disposal method that would be applicable to all EO users and would not result in any wastewater impacts. Therefore, the nationwide wastewater impacts calculated for this control device shown in Table 6-2 represent the maximum potential wastewater impacts. Because of ethylene glycol recycling, the actual impacts are expected to be lower.

6.3 SOLID WASTE IMPACTS

Solid waste impacts could occur if the owners or operators of EO sterilization facilities choose to landfill spent reactant from the gas/solid reactor used to control aeration room emissions. However, the reactant replacement costs were developed based on spent reactant being returned to the vendor for recycling because this alternative was more cost-effective. Therefore, the nationwide solid waste impacts calculated for this control device shown in Table 6-2 represent the maximum potential solid waste impacts. Because of spent reactant recycling, the actual impacts are expected to be lower.

Additionally, if an owner or operator of an EO sterilization facility chooses to control emissions with a catalytic oxidizer, solid waste impacts may occur if the spent catalyst is landfilled.

6.4 ENERGY IMPACTS

The energy requirements for acid-water scrubbers are considerably less than those of the gas/solid reactor fan. Energy requirements for each of the regulatory alternatives are also presented in Table 6-2. If a catalytic oxidizer is used at a facility to control emissions, energy impacts will be considerably higher.

TABLE 6-2. POTENTIAL NATIONWIDE WASTEWATER, SOLID WASTE, AND ENERGY IMPACTS

Regulatory Alternative	Total annual wastewater production, m ³ (gal) ^{a b}	Total annual solid waste production, Mg/(tons) ^{c d}	Total annual electricity consumption, Kw/hr (000's)
A	2,150 (569,000)	190 (209)	4,600
B	2,140 (566,000)	137 (151)	2,700
C	2,140 (566,000)	137 (151)	2,700
D	2,140 (566,000)	0	0
E	2,120 (561,000)	0	0

^aActual impacts anticipated to be zero because of recycling of ethylene glycol.

^bApproximately 60 percent (by volume) of wastewater is composed of ethylene glycol.

^cActual impacts anticipated to be zero because of recycling of reactant.

^dBased on the use of gas/solid reactor.

Source: U. S. EPA Ethylene Oxide Commercial Sterilization Data Base, 1986, 1988.

6.5 OTHER ENVIRONMENTAL CONCERNS

6.5.1 Irreversible and Irretrievable Commitment of Resources

Regulatory compliance would not preclude the development of future control options nor would such compliance curtail any beneficial use of the environment. No long-term environmental losses would result from regulatory compliance by commercial sterilization facilities.

6.5.2 Environmental Impact of Delayed Standards

Delaying the standards would result in possible solid waste impact reductions, but the reductions would be minimal compared with the air quality benefits attributable to promulgation of the standards. There do not appear to be any emerging emission control technologies that achieve greater emissions reductions or have significantly lower costs than the control devices considered here. Consequently, there are no benefits or advantages to delaying the proposed standards.

6.6 REFERENCES FOR CHAPTER 6

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5. Telecon. Srebro, S., MRI, with K. Dalton. High Valley Chemicals. March 16, 1989. Discussion about recovery of ethylene glycol from ethylene oxide scrubbing liquor.
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7.0 EMISSION CONTROL COSTS

This chapter presents a summary of the methodology used to develop emission control cost estimates for 188 of the 196 facilities (8 State department of agriculture mobile beehive fumigation units were not included in this cost analysis) in the 1989 EPA commercial sterilization (CS) data base. These 188 CS facilities operate a total of 404 sterilization chambers. A method for estimating EO emission control costs for sterilizer vents at CS facilities is presented in Section 7.1. Cost information for chamber exhaust and aeration room controls is discussed in Sections 7.2 and 7.3, respectively. The results of the cost analyses are presented in Section 7.4, and Section 7.5 presents other cost considerations.

Costs are further explained in Appendix E. Appendix E includes: (1) costs for acid-water scrubbers (Section E.1); (2) sample calculations of the equations used to develop capital and annual costs for acid-water scrubbers (Section E.2); (3) aeration room cost analysis (Section E.3); (4) capital and annual control costs for the sterilizer chamber, chamber exhaust, and aeration room vent(s) at an example facility (Section E.4); (5) a breakdown of manifolding costs for these three vents (Section E.5); and (6) the cost indices and conversion factors used to convert costs to fourth quarter 1987 dollars (Section E.6).

Costs presented in this chapter are in fourth quarter 1987 dollars and are for existing facilities only. No new facilities are anticipated.

7.1 STERILIZER VENT CONTROL COSTS

This section describes a method for estimating emission control costs for sterilizer vent(s) and vacuum pump drains at commercial sterilization facilities. Acid hydrolysis (i.e., acid-water scrubbing) was chosen as the basis for the costing procedure because this control technique currently is known to be used at 28 commercial sterilization facilities, representing a variety of industries and a wide range of sterilizer chamber sizes (7 to 274 cubic meters [m^3] [264 to 9,800 cubic feet {ft³}}).^{1,2} This control technique is also the most cost effective of the technologies in use.³ A detailed review of the available test data indicated that 99.0 percent is the maximum EO removal efficiency that acid hydrolysis techniques can achieve on a continuous basis.⁴ Therefore, 99.0 percent was used to calculate the emission reductions.

The costing procedure presented in this section has been used to develop emission control costs for the 188 commercial sterilization facilities represented in the 1989 EPA CS data base.⁵ (See Chapter 3 for a description of how the data base was developed.) Detailed example calculations for a typical commercial sterilization facility are given in Appendix E, Section E.4. Because these costs depend on sterilizer volume, the number of sterilizers, and annual EO use, example cost calculations for the sterilizer vent and chamber exhaust controls were provided for only one facility. However, the methodology for determining example costs for sterilizer vent and chamber exhaust emission controls was applied to all plants represented in the CS database. Therefore, the example costs provided in Appendix E, Section E.4, apply to all commercial sterilization facilities. However, because the methodology used to develop control costs for the aeration room is more complex, facility-specific costs are included in Appendix E, Section E.3, to supplement Tables E-12 and E-13 in Section E.4.

7.1.1 Description of Components Costed

The following components were costed: (1) an acid-water scrubber, (2) water-sealed vacuum pump(s) with closed-loop recirculation, (3) piping for manifolding the chambers to the existing control device or to a scrubber, (4) operating materials (i.e., chemicals and chlorine filters), (5) scrubber effluent disposal, and (6) labor.

Scrubber prices (freight-on-board [F.O.B.]) are listed in Table E-1. The capital costs associated with the scrubber and the piping system (for manifolding) are presented in Appendix E, Sections E.2 and E.5, respectively. The costs of operating materials, as well as the shipping charges used for computing disposal costs for the spent scrubber solution, are also presented in Appendix E, Section E.2.

7.1.2 General Assumptions

Scrubbers were not costed for facilities that had existing sterilizer vent control devices with efficiencies greater than or equal to 98-percent. Because of the chemical/physical characteristics of ethylene oxide as explained in Section 3.4.1, control devices operating at 98-percent efficiency (e.g., flares) may be assumed to operate at 99-percent efficiency. If a facility had a control device with an efficiency below 98 percent, a scrubber to remove 99.0 percent of the remaining emissions was costed. If a facility had an existing control but had uncontrolled chambers, it was assumed that the uncontrolled chambers were manifolded to the control device and that the existing control device had the capacity to control the additional emissions from the uncontrolled chambers.

Chamber volume was used as the basis for scrubber sizing. The relationship of chamber volume to a typical scrubber size is presented in Table E-1.

If a facility had three or more sterilization chambers, the scrubber costed was chosen based on the sum of the volumes of the two largest chambers at that facility. This methodology simulates the cost of controlling emissions from a facility if two chambers at that facility were to be evacuated

simultaneously. If a facility had two chambers, the scrubber was selected based on the volume of the larger chamber. For facilities with only two chambers, it was assumed that the sterilization cycles could be staggered so that the chambers would not be evacuated simultaneously.⁵

Costs were developed for recirculating-fluid vacuum pumps to control drain emissions normally associated with once-through, water-sealed vacuum pumps. Each sterilization chamber at a facility was costed for a recirculating-fluid vacuum pump unless the chamber had a control device that utilized a recirculating-fluid vacuum pump or a recirculating-fluid vacuum pump was already in place.

Piping costs for existing low-efficiency control devices were calculated based on the assumption that all sterilizers at a facility could be manifolded to the existing control device. An acid-water scrubber could then be manifolded to the existing control device to handle the remaining emissions. For facilities that had existing high-efficiency control devices, piping was costed to manifold any uncontrolled chambers to the existing control device. Otherwise, piping was costed to manifold all sterilizer chambers to an acid-water scrubber.

The disposal cost for the aqueous ethylene glycol solution produced by the acid-water scrubbers was computed as the cost to ship the solution, either in 55-gallon drums or in a tank truck, depending on quantity, to a recovery facility. Three recovery facilities that will accept the ethylene glycol on a no cost/no payment agreement were identified.⁶⁻⁸ Transportation costs were calculated by assuming that most CS facilities (except those in Puerto Rico) are located within 1,000 miles of one of the three known recovery facilities.⁵ This method of disposal was chosen because an earlier investigation of alternative disposal methods indicated that (1) discharging ethylene glycol to municipal wastewater treatment plants is a disposal method that may not be available to all sterilization facilities and (2) hauling by a waste disposal company would be costly for most sterilization facilities.

7.2 CHAMBER EXHAUST CONTROL COSTS

This section describes a method for estimating control costs for chamber exhausts. Although three types of control devices (i.e., catalytic oxidizers, gas/solid reactors, and acid-water scrubbers) are theoretically applicable to chamber exhaust emissions, none are currently in operation controlling chamber exhaust emissions. The costs of all three control devices were estimated. However, only the costs of the least expensive option, acid-water scrubbers, are presented here. Normally, an efficiency of 99.0 percent is used for an acid-water scrubber controlling sterilizer vent emissions. However, due to the differences in emission stream characteristics between the sterilizer vent and the chamber exhaust, an efficiency of 98 percent was used as a best-case estimate for an acid-water scrubber controlling the chamber exhaust.

Because both the sterilizer chamber and chamber exhaust vent use acid-water scrubbers to control EO emissions, the calculations used to determine annual operating costs (in Appendix E, Section E.2) for chamber exhaust controls are similar to those for the sterilizer vent. The main difference is that the acid-water scrubber for the chamber exhaust controls only 2 percent of the total facility EO use at an efficiency of 98 percent, whereas the sterilizer vent scrubber controls 95 percent of the total facility EO use at an efficiency of 99 percent. Capital costs for the chamber exhaust are based on a scrubber sized to control a flow rate of either 84 or 168 m³/min (3,000 or 6,000 ft³/min) (shown in Table E-1), ductwork for manifolding the chamber exhaust(s) to a common control (Table E-15), and associated installation costs. A breakdown of control costs for the chamber exhaust is included in Table E-11.

7.2.1 Description of Components Costed

The following components were costed: (1) an acid-water scrubber, (2) ductwork for manifolding vents, (3) operating materials, (4) scrubber effluent disposal, and (5) labor. Because of the extreme differences in ethylene oxide concentrations and the flow rates emitted from the emission

vents, manifolding was only costed between multiple emissions sources of the same type (e.g., manifolding multiple sterilizer vents or chamber exhaust vents or aeration room vents).

7.2.2 General Assumptions

In November 1989, the Health Industry Manufacturer's Association (HIMA) conducted a survey of 14 companies (23 facilities) to determine the prevalence of chamber exhaust use. Although these facilities represent only 12 percent of the facilities in the EPA CS data base, they represent 40 percent of the annual EO use. Of the 156 chambers these companies operate, 35 chambers (22 percent) do not have chamber exhausts.⁹ Typically, these chambers are small in size, i.e., less than 7 m³ (250 ft³). Therefore, based on this HIMA survey, sterilizer chambers that were smaller than 7 m³ (250 ft³) were not assumed to have chamber exhaust and were not costed for control devices. It was assumed that these facilities can perform more air washes to reduce worker exposure to EO, which is the purpose of the chamber exhaust.

A flow rate of 84 m³/min (3,000 ft³/min) was assumed for chamber exhaust emissions and served as the basis for sizing an acid-water scrubber to control chamber exhausts. For this cost analysis, if a facility has more than two sterilizers, the total emission flow rate to the control is assumed to be 168 m³/min (6,000 ft³/min). This methodology simulates the control cost if two sterilizers were to vent to the chamber exhaust simultaneously. If a facility has one or two sterilizers, the emission flow rate is assumed to be 84 m³/min (3,000 ft³/min). This methodology is based on the assumption that a facility with only two sterilizers will rarely need to vent the chamber exhausts simultaneously and is consistent with the methodology used to develop sterilizer vent costs.⁵

The scrubber effluent disposal costs for the chamber exhaust scrubber are the same as those for the sterilizer vent control.

7.3 AERATION ROOM CONTROL COSTS

This section describes a method for estimating emission control costs for aeration rooms at CS facilities.

Initially, costs were developed for gas/solid reactors and catalytic oxidizers to control aeration room emissions. Because the gas/solid reactor was the most cost-effective of the controls considered, it was selected as the basis for the cost estimating procedure. However, catalytic oxidizers are equally viable and effective control devices; therefore, cost estimating tables for catalytic oxidizers, similar to those developed for gas/solid reactors, are included in Appendix E (Tables E-9 and E-13). For both of these control devices, facilities and test reports reported a 99-percent efficiency; therefore, 99 percent was used as a best-case estimate of control device efficiency.

A gas/solid reactor was costed for 185 of the 188 CS facilities. Three facilities already controlled aeration room emissions with catalytic oxidizers and were, therefore, not included in the cost analysis. A breakdown of the costs of controlling aeration emissions with gas/solid reactors is included in Table E-8. A breakdown of the manifolding costs is shown in Table E-16.

7.3.1 Description of Components Costed

The following components were costed: (1) gas/solid reactor(s), (2) insulated shipping containers (aeration chambers) to take the place of aeration rooms, (3) ductwork to manifold the aeration chambers to a common control device, (4) operating materials (including utilities), and (5) labor.

7.3.2 General Assumptions

Aeration chambers were costed to replace existing aeration rooms because emission flow rates from aeration rooms are typically high (greater than $280 \text{ m}^3/\text{min}$ [$10,000 \text{ ft}^3/\text{min}$]) with very low (less than 2 parts per million [ppm]) EO concentrations. By reducing the aeration room size, the emissions can be more easily controlled because the flow rate is decreased, and the EO concentration is increased. Therefore, it was assumed that aeration chambers could be used to replace all existing aeration processes. The aeration chambers were assumed to be unheated and, consequently, at ambient temperature. No decrease in aeration time was attributed to temperature for this cost analysis.

A regression analysis was performed on aeration room data received from 35 facilities.¹⁰ This analysis was used to correlate the number of model aeration chambers (necessary to replace existing aeration processes) to a facility's EO use so that aeration chambers could be assigned to facilities to replace existing aeration rooms.

The result of the correlation is that facilities that use 2.27 Mg/yr (5,000 lb/yr) or less of EO were assigned one aeration chamber; however, no cost was attributed to this unit because facilities that use this amount of EO typically have aeration rooms smaller than the aeration chamber. Facilities that use 2.27 to 4.54 Mg/yr (5,000 to 10,000 lb/yr) EO were costed for one aeration chamber. Facilities that use between 4.54 and 36.3 Mg/yr (10,000 and 80,000 lb/yr) EO were costed for aeration chambers based on the equation $Y = 1.35 \times (10^{-4})X$. Facilities that use more than 36.3 Mg/yr (80,000 lb/yr) were costed for aeration chambers based on the equation $Y = 2.9 (10^{-5})X + 8.6$ (where Y = number of aeration chambers and X = annual EO use, lb/yr, for both equations).

Cost estimates for a 28 m³/min (1,000 ft³/min) gas/solid reactor were obtained from a vendor. This gas/solid reactor is capable of handling EO emission concentrations up to 100 ppm.¹¹ Costs were extrapolated using an equation provided by the vendor to determine the cost of an 84 m³/min (3,000 ft³/min) gas/solid reactor. It was assumed that a maximum of 12 aeration chambers (2 parallel sets of 6 in series) could be vented to a control unit. The emission flow rate from each of these aeration chambers was assumed to be 7 m³/min (250 ft³/min), and the number of control units was selected so as to minimize capital costs.¹¹

Disposal costs for the spent gas/solid reactant were calculated for a transportation distance of 1,500 miles. This cost was based on the assumption that the reactant could be returned to the vendor for recycling on a no-charge, no-credit basis. A distance of 1,500 miles was used because most facilities (except those in Puerto Rico) are located within 1,500 miles of the manufacturer of the reactant.¹¹

7.4 RESULTS OF COST ANALYSIS

The nationwide cost impacts associated with each of the regulatory alternatives are shown in Table 7-1. Table 7-2, shows the cost impacts on three representative facilities. A "facility" in this case includes the sterilization vent, chamber exhaust vent, and aeration room vent emissions. These facilities were selected to represent the median facility (with regard to annual EO use and cumulative sterilizer chamber volume) in each of the following annual EO use ranges: <272, 272 to 18,150, and >18,150 kg/yr (<600, 600 to 40,000, and >40,000 lb/yr). A representative facility was not selected for facilities that use less than 11 kg/yr (25 lb/yr) EO because such a facility does not exist. The facilities that were selected represent small, medium, and large facilities that use 228, 3,963, and 67,604 kg/yr (504, 8,736, and 149,000 lb/yr) of EO; and have cumulative sterilizer volumes of 5.7, 28, and 112 m³ (204, 1,000, and 4,002 ft³), respectively.

7.5 OTHER COST CONSIDERATIONS

In addition to the costs described above, costs to comply with other Federal rules or regulations may be incurred by commercial sterilization facilities. These costs are described in the following section.

At CS facilities where workers handle or are near product during the sterilization process, measures must be taken to reduce EO worker exposure to less than 1 ppm per 8-hour time-weighted average concentration. In most facilities with cumulative sterilizer volumes less than 7 m³ (250 ft³) worker exposure is minimized using the chamber exhaust, which evacuates EO-laden air from the chamber while workers are loading/unloading the sterilizer chamber. Two of the regulatory alternatives require add-on controls for the chamber exhaust. If a facility were to elect to disable the chamber exhaust in lieu of the add-on control there would be additional costs to ensure continued OSHA compliance.

TABLE 7-1. NATIONWIDE REGULATORY ALTERNATIVE COST IMPACTS

Regulatory Alternative	Emission reduction, %	EO use cutoff			Total annual costs, \$/MM	Emission reduction, Mg/yr (tons/yr)	Cost effectiveness \$/Mg (\$/ton)	Incremental cost effectiveness, \$/Mg (\$/ton)
		Sterilizer vent, kg/yr (lb/yr)	Aeration room, kg/yr (lb/yr)	Chamber exhaust				
A	99	11 (25)	11 (25)	Add-on controls ^a	12	1,061 (1,170)	11,300 (10,300)	47,000 (133,000)
B	97	272 (600)	18,144 (40,000)	Add-on controls ^a	9.2	1,042 (1,149)	8,800 (8,000)	74,000 (67,000)
C	94	272 (600)	18,144 (40,000)	Status quo ^b	6.4	1,004 (1,107)	6,400 (5,800)	51,000 (46,000)
D	90	272 (600)	N/A	Status quo ^b	4.3	963 (1,062)	4,500 (4,050)	45,000 (41,000)
E	89	907 (2,000)	N/A	Status quo ^b	3.8	952 (1,049)	4,000 (3,600)	4,000 (3,600)

^aEthylene oxide use cutoff same as for sterilizer vent.

^bStatus quo means that baseline chambers exhaust emissions are not exceeded.

TABLE 7-2. REPRESENTATIVE FACILITY COST IMPACTS

Regulatory Alternative	Facility EO use, kg/yr (lb/yr)	Sterilizer control costs, \$1,000		Chamber exhaust control costs, \$1,000		Aeration room control costs, \$1,000		Total emission reduction Mg (ton)	Total cost effectiveness, \$/Mg (\$/ton)
		Capital	Annual	Capital	Annual	Capital	Annual		
A	228 (504)	82.4	22.1	a	a	27.5	9.3	0.226 (0.249)	139,000
	3,963 (8,736)	175	43.7	66.8	18.8	45.9	13	3.92 (4.32)	(126,000)
	67,604 (149,000)	309	103	118	30.6	274	73.4	66.9 (73.7)	19,300 (17,500)
B	228 (504)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	3,963 (8,736)	175	43.7	66.8	18.8	N/A	N/A	3.8 (4.19)	16,500 (14,900)
	67,604 (149,000)	309	103	118	30.6	274	73.4	66.9 (73.7)	3,090 (2,810)
C	228 (504)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	3,963 (8,736)	175	43.7	N/A	N/A	N/A	N/A	3.73 (4.11)	11,700 (10,600)
	67,604 (149,000)	309	103	N/A	N/A	274	73.4	65.6 (72.3)	2,690 (2,440)
D	228 (504)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	3,963 (8,736)	175	43.7	N/A	N/A	N/A	N/A	3.73 (4.11)	11,700 (10,600)
	67,604 (149,000)	309	103	N/A	N/A	N/A	N/A	63.6 (70.1)	1,620 (1,470)
E	228 (504)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	3,963 (8,736)	175	43.7	N/A	N/A	N/A	N/A	3.73 (4.11)	11,700 (10,600)
	67,604 (149,000)	309	103	N/A	N/A	N/A	N/A	63.6 (70.1)	1,620 (1,470)

7.6 REFERENCES FOR CHAPTER 7

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8.0 THE ECONOMIC IMPACTS OF THE CANDIDATE NESHAP CONTROLS

8.1 INTRODUCTION

Companies performing ethylene oxide (EO) sterilization fall into two general groups: in-house sterilizers and contract sterilizers. In-house sterilizers are companies that produce the goods needing sterilization. As part of their production process, they also sterilize the products. Also included in this group are laboratories, museums, and libraries. These in-house sterilizers do not produce goods needing sterilization, but, like the other in-house sterilizers, sterilization is a small but necessary part of their operations. Museums, for example, specialize in preserving and displaying artworks or artifacts. To be preserved, some of these artifacts must be sterilized or fumigated. Sterilization is only a very small part of the activities carried on by museums; some of them choose to perform it onsite, while others send their artifacts offsite to a contract sterilizer.

Contract sterilizers are companies that specialize in sterilization/fumigation, so sterilization is a major part of their business. They do not, in general, produce any of the goods being sterilized; rather, they offer the service of sterilization to other producers.

This chapter identifies the industries affected by this regulation and evaluates the economic impacts of three possible control options. First, the industries that perform EO sterilization are described; then the industries producing

products requiring sterilization are profiled. Finally, the effects of the control options on these industries are assessed.

8.2 ETHYLENE OXIDE STERILIZATION

8.2.1 Process Inputs

The major capital equipment requirement for sterilization is the sterilization chamber. The 188 facilities covered in this profile operate 404 chambers, an average of 2.2 chambers per facility. The number of chambers per facility ranges from one to nine. Chamber sizes range from 0.01 cubic meters (m^3) (0.35 cubic feet [ft^3]) to 177 m^3 (6,250 ft^3) and average about 16 m^3 (565 ft^3).¹ A typical chamber has a useful life of approximately 10 years; at the end of that time, the salvage value of the chamber is less than 1 percent of the initial capital investment.²

Certain design characteristics of the sterilization chamber are determined by the gas to be used for sterilization. These design characteristics limit the possibility of switching gases in the short run. When pure EO is used, the chamber instrumentation and room must be explosion-proof.³ Pure EO chambers must also operate with a deep vacuum to rid the chamber of oxygen. Chambers that use an EO/ CO_2 mixture, which requires a substantially higher operating pressure than other gases, have to meet higher standards of construction to withstand the pressure.⁴

The various chamber specifications are not mutually exclusive. For example, a chamber designed to withstand the high operating pressure associated with the EO/ CO_2 mixture can also accommodate the lower pressures required by other sterilant gases. Therefore, some facilities can have chambers with the characteristics necessary for use with more than one type of sterilant gas. Consequently, these facilities can alternate between gases to achieve optimal combinations of product and sterilant gas for each sterilization cycle. Facilities involved in testing and research and those that sterilize a wide variety of products are more likely to operate chambers in this manner.

Other equipment required for the sterilization process includes:

1. A pump to create a vacuum in the chamber; and
2. A pump to force sterilant gas or air into the chamber.

Some facilities also have a separate room for the aeration step of the process, although aeration at some facilities can be accomplished in the sterilization chamber so that products do not have to be moved.

Labor requirements for EO sterilization are usually higher than for other types of sterilization (e.g., thermal or radiation). Each sterilization cycle must be closely monitored because several critical process variables require careful attention.⁵ In addition, sterilization with pure EO requires strict safety precautions and extensive monitoring by facility personnel because pure EO is flammable.

8.3 SUBSTITUTION POSSIBILITIES AND THE PRICE ELASTICITY OF DEMAND

The extent of substitution between the EO-based gases is limited by the characteristics of the sterilization chamber and the compatibility of the sterilizing medium with the products being sterilized. As noted earlier, both pure EO and the EO/CO₂ mixtures may require specially designed sterilization chambers. Chambers may be modified to use pure EO, but industry standards prohibit modifying chambers for use with the EO/CO₂ mixture. However, the different pressures under which sterilization is performed for each sterilant gas can damage some products or packaging. Consequently, substituting with sterilant gases that require extremely high or low operating pressures is limited by the characteristics of the products being sterilized.

Gamma radiation sterilization can substitute for EO sterilization for many products. Unlike EO, radiation can sterilize liquids and products in vapor-tight packages; however, it discolors plastics and damages Teflon and acetyl delrin.^{4,5} Gamma radiation cannot be used to sterilize pharmaceuticals because the radiation may alter the chemical structure of the drugs. Gamma radiation is expected to make some additional inroads into the EO market for sterilization.² Although gamma radiation is a likely substitute for EO sterilization, safety

concerns regarding transportation and disposal of the radiation source and the cost of the radioactive cobalt used as a radiation source will probably limit any increase in the percentage of the products sterilized by radiation. [Several other chemical substitutes for EO exist, but their use is more limited than gamma radiation; the substitution possibilities for these chemicals are discussed in later sections in conjunction with the appropriate end products.]

The importance of the sterilization procedure in the overall production process of many products presumably has a profound effect on its demand elasticity (i.e., the responsiveness of quantity demanded to a change in the price of sterilization services). Four main issues influence the elasticity of demand for a factor within an industry.⁶ Specifically, the elasticity of demand should vary directly with the elasticity of demand for the final product, the factor's share of the costs of production, the elasticity of supply of other factors, and the elasticity of substitution between the factors.

These influences suggest that the demand for sterilization within the relevant industries is relatively inelastic. This conclusion is based in part on the low ratio between the cost of sterilization and the total cost of production.⁷ Additionally, the elasticity of substitution between factors of production within the industries is relatively low; precautions taken to minimize contamination during production do not necessarily lessen the need for sterilization but enhance the effectiveness of the process. Generalizations regarding the elasticity of demand for the final product and the elasticity of supply of other factors are not possible due to variations from industry to industry.

8.4 SUPPLY OF EO STERILIZATION SERVICES

This section profiles the facilities that sterilize/fumigate medical devices and other miscellaneous products with EO, excluding sterilization activities in hospitals. For simplicity, we refer to this process simply as sterilization. For a variety of reasons discussed later in this section,

sterilization does not form a cohesive industry but is instead a part of the production process in several industries. Therefore, this profile will be limited in the scope of its analysis. The most important limiting factor is the lack of data on sterilization as a separate step in the production process. Consequently, commercial sterilizers are grouped here by industry; sterilization is then analyzed within the context of that industry.

8.4.1 National Summary of Ethylene Oxide Sterilization

The economic analysis presented in this chapter covers 188 sterilization facilities for which data are available. About half of the 188 facilities are suppliers of medical devices or other health-related items; the other facilities engage in several miscellaneous sterilization and fumigation operations (discussed later).

In 1988, approximately 1,913 megagrams (Mg) (4.22 million pounds [lb]) of EO was used for sterilization purposes by the 188 facilities covered in this analysis. [The EPA commercial sterilization database contains 1988 data for 32 facilities, the remainder are 1985 or 1986 values; for simplicity, 1988 will be referred to as the base year.] Table 8-1 presents some summary statistics on the use of the sterilant gases at the 188 facilities, separated into two categories--EO use and total gas use. The tremendously wide range in the use of sterilant gas per facility is noteworthy.

As mentioned above, several characteristics of the sterilization process make it difficult to profile the process as a discrete industry. The most important characteristic stems from the role of sterilization in the overall production process. Except for contract sterilizers, the sterilization process is an intermediate step in the production process. Therefore, separating sterilization from the production of the sterilized products is difficult. Another difficulty is the absence of a Standard Industrial Classification (SIC) code listing for sterilization either separately or within the classifications for the industries that employ this process. Furthermore, EO

TABLE 8-1. SUMMARY STATISTICS ON THE USE OF STERILANT GAS
AT 188 COMMERCIAL STERILIZATION FACILITIES, 1988

		Ethylene oxide	Total gas
		1,913 (1,883)	6,560 (6,456)
Total use	Mg/yr (tons/yr)		
Use per facility			
Average	kg/yr (lb/yr)	10,179 (22,441)	34,897 (76,935)
Range	kg/yr (lb/yr)	1-129,090 (2-284,594)	6-359,400 (13-792,341)
Use per chamber			
Average	kg/yr (lb/yr)	4,737 (10,443)	16,239 (35,801)
Range	kg/yr (lb/yr)	0.1-62,045 (0.2-136,786)	0.1-168,000 (0.2-370,382)

sterilization accounts for only 50 to 60 percent of all sterilization activities.⁴ Finally, the diversity and specialization of the industries that sterilize products limit the amount of data available for this profile.

8.4.2 Industry Groups Supplying EO Sterilization Services

Several main categories of facilities sterilize some portion of their output:

1. Medical device suppliers;
2. Other health-related suppliers;
3. Pharmaceutical manufacturers and other drug-related manufacturers;
4. Spice manufacturers and other food-related manufacturers;
5. Museums and libraries;
6. Laboratories (research, testing, and animal breeding); and
7. Contract sterilizers.

Table 8-2 summarizes the specific SIC codes associated with these industry categories and the number of facilities in each. As might be expected from the large number of SIC codes, the 188 sterilization facilities sterilize a wide variety of products. These products include surgical gloves and hypodermic needles sterilized by medical device suppliers, books fumigated by libraries and museums, and spices fumigated by spice manufacturers.

The sterilization processes used by the above industries have several similarities. However, a distinction can be made between in-house sterilization and contract sterilization. A majority of the facilities covered in this profile operate a sterilization chamber at the same location as the remainder of the production process. The exception to this rule is the subset of commercial sterilizers that sterilize products for other companies on a contract basis. Not only do contract sterilizers accept a variety of products for sterilization, but they may also supervise the final distribution of the products. It should be noted that the distinction between these two types of

**TABLE 8-2. STANDARD INDUSTRIAL CLASSIFICATION CODES FOR
188 COMMERCIAL STERILIZATION FACILITIES, 1988**

SIC Code	No. of facilities	Description of category
Medical device suppliers = 62		
3841	44	Surgical and medical instruments and apparatus
3842	18	Orthopedic, prosthetic, and surgical appliances and supplies
Other health-related suppliers = 24		
3079	7	Miscellaneous plastic products
3693	5	Radiographic X-ray, fluoroscopic X-ray, therapeutic X-ray, and other X-ray apparatus and tubes; electrochemical and electrotherapeutic apparatus
5086	4	Professional equipment and supplies
2211	1	Broad woven fabric mills, cotton
2821	2	Plastics materials, synthetic resins, and nonvulcanizable elastomers
2879	1	Pesticides and agricultural chemicals, NEC
3069	1	General industrial machinery and equipment NEC
3569	1	Electronic coils, transformers, and other inductors
3677	1	Electronic coils, transformers and other inductors
3999	1	Manufacturing industries, NEC
Pharmaceutical manufacturers = 39		
2834	34	Pharmaceutical preparations
5122	2	Drugs, drug proprietaries, and druggist's sundries
2831	2	Biological products
2833	1	Medicinal chemicals and botanical products
Spice manufacturers = 23		
2099	17	Food preparations, NEC
5149	3	Groceries and related products, NEC
2034	1	Dried and dehydrated fruits, vegetables, and soup mixes
2035	1	Pickled fruits and vegetables, vegetable sauces and seasonings, and salad dressings
2046	1	Wet corn milling
Museums and libraries = 13		
8411	11	Museums and art galleries
8231	2	Libraries and information centers
Laboratories = 10		
2790	4	Animal specialties, NEC
7391	2	Research and development labs
8071	1	Medical labs
8922	2	Noncommercial educational, scientific, and research organizations
7397	1	Commercial testing labs
Contract sterilizers = 17		
7399	14	Business services, NEC
7218	1	Industrial launderers
8091	2	Health and allied services, NEC

NEC = Not elsewhere classified.

sterilization is not always well defined. Some facilities, especially those within the medical device suppliers and pharmaceutical industries, sterilize their own products in-house and also accept products on a contract basis from other firms.⁸

8.4.2.1 Medical Device Suppliers. Sterilizers of medical devices (SIC 3841 and 3842) represent the largest single segment of commercial sterilizers covered in this analysis, including 62 of the 188 facilities. The total annual output of medical devices sterilized in the United States is estimated as 15 to 20 billion products, with at least 50 percent of these products sterilized with EO.¹

Some medical devices must be sterilized to be marketed. Ethylene oxide, especially the 12/88 mixture, is used for medical device sterilization because of its wide range of effectiveness. The FDA has set strict guidelines for medical device sterilizers to ensure that necessary levels of sterility are achieved. These guidelines, called Good Manufacturing Practices (GMP), include requirements for such things as preliminary testing, procedural supervision, quality assurance, and final labeling.⁵

The U.S. medical device supply industry has been changing rapidly because of cost containment measures, increased competition, and changes in the health care system. A trend toward consolidation among both buyers and sellers of medical devices has been evident. Many hospitals have formed buyers' groups or corporate buying arrangements for purchasing supplies. Consolidation has allowed suppliers to increase their efficiency and broaden their product and distribution bases. Declining hospital occupancy and shorter visits have decreased the demand for medical devices from hospitals. At the same time, demand for medical devices from outpatient facilities has experienced strong growth. The number of surgical procedures being performed has been growing, but a larger share of these procedures is being done on an outpatient basis.

Product quality is becoming a major issue in the medical device industry. Under pressure from the FDA and increasing competition, suppliers are striving to improve their

manufacturing processes and products. The surgical and medical instruments industry (SIC 3841) is expected to grow about 7 percent per year (in 1982 dollars) between 1989 and 1993. The surgical appliances and supplies industry (SIC 3842) is projected to grow at an annual rate of 8.5 percent during this time. According to the Census of Manufactures, there were 2,600 establishments in the surgical and medical instruments and surgical appliances and supplies industries (SIC 3841 and 3842) in 1987. Table 8-3 summarizes various statistics for these industries. Product data were collected for all products classified in either SIC 3841 or 3842 that are produced by all industries; industry data represent all facilities classified in either SIC 3841 or 3842, including their output of nonmedical products.^{9,10}

The data presented in Table 8-3 reveal several trends within the industry. The total value of shipments for medical device suppliers is given in current dollars and in 1982 dollars. Throughout the 1980's, the industry has shown strong, steady growth. Total employment has risen steadily since 1972, while the proportion of production workers has fallen slightly. In 1988, production workers made up 63 percent of the total work force, as compared with 69 percent in 1972. Growth in foreign markets, along with a lower value of the U.S. dollar relative to other currencies, has allowed U.S. manufacturers to increase exports of medical devices. Manufacturers of surgical and medical instruments (SIC 3841) increased exports by 17 percent between 1987 and 1988. Imports of these products also increased but at a slower rate (13.8 percent), allowing the trade surplus to grow by 29 percent. Exports of surgical appliances and supplies (SIC 3842) grew 25 percent during this time, while imports grew only 5.7 percent. Exports of medical devices are expected to remain high if the U.S. dollar does not appreciate substantially. Although the U.S. has consistently had an overall trade surplus in the medical device industry, it continues to have trade deficits with West Germany and Japan.⁹

TABLE 8-3. RECENT PERFORMANCE AND FORECAST DATA FOR MEDICAL
DEVICE SUPPLIERS (SIC 3841 AND 3842)^{a-c}

		1972	1975	1980	1985	1986	1987	1988	1989 ^d
Product data ^e									
Value of shipments	(10 ⁶ \$)	2,126	3,302	6,185	11,863	12,447	13,383	14,858	NA
Value of shipments	(10 ⁶ 1982 \$)	4,435	5,243	6,892	10,828	11,077	12,165	13,213	14,402
Industry data ^f									
Total employment	(10 ³ people)	78.4	94.4	113.1	137.7	140.3	139.4	147	NA
Production workers	(10 ³ people)	54.1	64.1	75.8	88.5	88	86.5	92.7	NA
Capital expenditures	(10 ⁶ \$)	89.5	157.6	281.0	551.2 ^h	471.7 ^h	552.7 ^h	NA	NA
Value added	(10 \$) ^g	1,559.0 ^g	2,240.9 ^g	4,077.3 ^g	8,503.2 ^h	8,954.8 ^h	10,619.8 ^h	NA	NA
Trade data									
Value of imports ⁱ	(10 ⁶ \$)	44.2	106.4	268.4	581	785	959	1,069	1,160
Value of exports ⁱ	(10 ⁶ \$)	217.6	432.0	698.0	1,124	1,275	1,486	1,790	2,060

NA = not available.

^aNumbers represent the sum of the values of the two industry groups.

^bSource: Years 1972, 1975, and 1985 are Reference 11 unless otherwise noted.

^cSource: Years 1985 through 1989 are Reference 12 unless otherwise noted.

^dForecast.

^eRepresents products classified in SIC codes 3841 and 3842 produced by all industries.

^fRepresents all facilities classified as SIC 3841 and 3842.

^gSource: 13.

^hSource: 10.

ⁱDeveloped by International Trade Administration.

Although a wide range of products is included under the broad category of medical devices, generalizing about the importance of the products is still possible. Medical equipment is a basic part of health care service, which is a necessary service. Therefore, the elasticity of demand for medical devices should be highly inelastic. However, the trends mentioned above (increased price competition among health care facilities and increased use of alternatives to hospitals) may indicate that the demand for medical devices is becoming more elastic. The availability of imports may also increase the elasticity of demand for domestically produced medical devices.

Table 8-4 shows some summary statistics on the sterilization chambers and sterilant gases used by the 62 medical device suppliers included in this study. These 62 facilities operated a total of 145 EO sterilization chambers in 1988, an average of 2.3 per facility. The number of chambers per facility varied from one to eight. Average chamber volume per facility was 40.1 m^3 ($1,416.0 \text{ ft}^3$) but covered a wide range from 0.03 m^3 (1.06 ft^3) to 232 m^3 ($8,193 \text{ ft}^3$). In 1988, these 62 facilities used 665 Mg (654 tons) of EO, slightly under 11 Mg (10 tons) per facility. Like chamber volume per facility, EO use varied widely from 0.01 Mg (0.01 tons) to 109 Mg (107 tons). Total gas use, which averaged 42 Mg (41 tons) per facility, also covered a wide range; the smallest user reported 0.05 Mg (0.06 tons) and the largest reported 511 Mg (503 tons).¹

By subtracting EO use from the total gas use, and then dividing by EO use, an inert-gas ratio is obtained. This ratio indicates the extent of reliance on pure EO versus mixed sterilant gases. In particular, a ratio near zero would suggest extensive reliance on pure EO (because EO use and total gas use would be almost identical), but a much higher ratio would indicate greater use of sterilant mixtures, such as 12/88. During 1988, the inert-gas ratio for the 62 medical device suppliers was 2.88.

8.4.2.2 Other Health-Related Suppliers. Twenty-four facilities were included in this study that produce some type of

TABLE 8-4. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 62 MEDICAL DEVICE SUPPLIERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 145			
Number per facility	2.3	1.6	1 - 7
Chamber volume per facility, m ³ (ft ³)	40.1 (1,416.1)	37.9 (1,338.4)	0.03 - 232 (1.06 - 8,193)
Ethylene oxide use = 665.6, Mg/yr (655.1 tons)			
Use per facility, Mg/yr (tons)	10.7 (10.5)	6.9 (6.8)	<0.05 - 109.1 (<0.05 - 107.3)
Total gas use = 2,576.7 Mg/yr (2,536.0 tons)			
Use per facility, Mg/yr (tons)	41.6 (40.9)	76.2 (75.0)	0.05 - 511.2 (0.5 - 503)

health-related supplies but are classified under a more general SIC code (see Table 8-2). For example, five facilities have a primary SIC code that involves the manufacturing of X-ray equipment and nine facilities manufacture various plastic products. The large number of SIC codes illustrates the diversity of industries that sterilize health-related equipment with EO. For this reason, the value of shipments in Table 8-3 was presented on a product basis rather than on an industry basis. No other data specific to the relevant SIC codes will be presented.

Table 8-5 provides some summary statistics on the sterilization chambers and sterilant gas used by the 24 other health-related suppliers included in this study. These 24 facilities operated a total of 53 sterilization chambers in 1988, an average of 2.2 per facility. This is slightly lower than the medical device suppliers group, which averaged 2.3 chambers per facility.

The other health-related suppliers used 276 Mg (271 tons) of EO in 1988. They averaged 11.5 Mg (11.3 tons) of EO per facility, covering a range of 0.002 Mg (0.0022 tons) to 129.0 Mg (127.0 tons). Overall, these facilities used less EO than did the medical device suppliers. However, their EO use per facility and their total gas use per facility are slightly higher than those of medical device suppliers. The inert gas ratio for other health-related suppliers was 2.46.

8.4.2.3 Pharmaceutical Manufacturers. The broad category of pharmaceutical manufacturers includes those facilities whose SIC code was 2831, 2832, 2834, or 5122. These facilities are all connected with pharmaceutical preparations or other medicinal or biological products as manufacturers or, in some cases, as wholesalers. However, a vast majority of the facilities are classified as SIC 2834. Therefore, the profile of pharmaceutical manufacturers is focused on that industry group. Sterilization has a variety of uses in this industry, but it is as closely tied to the ultimate safety and effectiveness of the products as is the medical device industry.

TABLE 8-5. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 24 OTHER HEALTH-RELATED SUPPLIERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 53			
Number per facility	2.2	1.5	1 - 6
Chamber volume per facility, m ³ (ft ³)	41.3 (1,458.5)	58.4 (2,062.4)	0.4 - 207.2 (14.1 - 7,317.2)
Ethylene oxide use = 275.5 Mg/yr (271.2 tons)			
Use per facility, Mg/yr (tons)	11.5 (11.3)	7.07 (6.96)	<0.05 - 129.1 (<0.05 - 127.1)
Total gas use = 952.5 Mg/yr, (937.5 tons)			
Use per facility, Mg/yr (tons))	39.7 (39.1)	51.1 (50.3)	0.05 - 152.2 (0.05-149.8)

The pharmaceutical industry shows several interesting trends. Pharmaceutical companies continue to spend increasing amounts on research and development: they spent \$5.4 billion in 1987 and a record \$6 billion in 1988. Experts expect that the high cost of research and development will lead to consolidation, especially among small specialty manufacturers. Patent piracy remains a problem for this industry. Manufacturers lost an estimated \$2 billion to patent pirates in 1988. Sales of generic drugs will continue to grow as patents on existing drugs expire. Generic drugs currently make up about 12 percent of the prescription market and will probably account for 30 percent by 1993. The pharmaceutical industry also expects strong growth in the market for over-the-counter drugs as more drugs are made available for purchase without a prescription.⁹

The value of pharmaceutical product shipments rose an estimated 2.7 percent (in constant dollars) between 1987 and 1988. The U.S. Department of Commerce predicts that the industry will grow between 2 and 3 percent a year between 1989 and 1993. Factors contributing to this growth will include an increasing demand for drugs by an aging population, greater exports to developing countries, and improved productivity through computerization.⁹

According to the Census Bureau, a total of 718 facilities were classified under SIC code 2834 in 1987. Only 34 have been identified as commercial sterilizers.¹⁰ The pharmaceuticals group, as defined in this chapter, includes five additional facilities from SIC codes 5122, 2831, and 2833. Table 9-6 reports recent performance and forecast data for all pharmaceutical manufacturers classified under SIC code 2834. The data are presented in much the same manner as in Table 8-3, with a distinction between industry and product data.

As shown in Table 8-6, the value of pharmaceutical shipments has increased steadily through the 1980's in both nominal and real terms. Industry employment, after falling in the early 1980's, has shown an upward trend since 1985. Capital expenditures decreased somewhat between 1985 and 1986 but

TABLE 8-6. RECENT PERFORMANCE AND FORECAST DATA FOR PHARMACEUTICAL MANUFACTURERS
(SIC 2834) ¹²

	1972	1975	1980	1985	1986	1987	1988	1989
Product data								
Value of shipments (10 ⁶ \$)	6,295	8,247	13,012	22,318	24,280	26,898	29,820	NA
Value of shipments (10 ⁶ 1982 \$)	12,422	14,202	15,974	17,283	18,836	19,213	19,735	20,290
Industry data								
Total employment (10 ³ people)	112.0	123.0	135.0	123.0	124.0	128.0	128.0	129.0
Production workers (10 ³ people)	57.0	60.2	68.4	58.4	58.7	59.4	60.7	61.3
Capital expenditures (10 ⁶ \$)	167.0	321.0	675.0	1,171.1 ^a	1,057.8 ^a	1,470.4 ^a	NA	NA
Value added (10 ⁶ \$)	5,640 ^b	6,923 ^b	11,048 ^b	19,095 ^a	20,598 ^a	23,868 ^a	NA	NA
Trade data								
Value of imports ^c (10 ⁶ \$)	14.5	33.9	61.6	216	157	164	202	245
Value of exports ^c (10 ⁶ \$)	182.0	270.0	421.0	691	648	675	840	1,050

NA = Not available.

^aSource: 10.

^bSource: 13.

^cDeveloped by International Trade Administration.

increased in 1987. In recent years, both imports and exports of pharmaceuticals have been increasing.

Table 8-7 contains some summary statistics on the sterilization chambers and sterilant gas used by the 39 pharmaceutical manufacturers included in this study.¹ These 39 facilities operated a total of 82 sterilization chambers in 1988, averaging 2.1 per facility. The average chamber volume per facility for pharmaceutical manufacturers is 29.2 m³ (1,031.2 ft³), with chamber volume ranging from 0.1 m³ to 147 m³ (3.5 ft³ to 5,191 ft³). Although the number of chambers per facility in the pharmaceuticals group roughly equals the number for the medical device suppliers group, the average chamber volume per facility for pharmaceutical manufacturers is about 70 percent of the average for medical device suppliers.

The pharmaceutical manufacturers used 416 Mg (409 tons) of EO in 1986, averaging 10.7 Mg (10.5 tons) per facility and varying from 0.01 Mg (0.01 tons) per facility to 84 Mg (82.7 tons) per facility. They also used 830 Mg (818.9 tons) of total gas, with an average of 21.3 Mg (21.0 tons) per facility and a range of 0.06 Mg to 92 Mg (0.06 to 90.5 tons) per facility. The ranges of both EO use and total gas use are much narrower for pharmaceutical manufacturers than they are for medical device suppliers. Finally, the inert-gas ratio for pharmaceuticals is 1.00, compared to a 2.88 ratio for the medical device suppliers.

8.4.2.4 Spice Manufacturers. Twenty-three of the 188 facilities in this study have been categorized as spice manufacturers. These firms fall into five SIC codes: 2099, 5149, 2034, 2035, and 2046. However, as shown in Table 8-2, about two-thirds of these firms are in SIC code 2099. Consequently, the discussion below focuses on this industry group.

About one-quarter of all spices manufactured in the United States are treated with EO to control fungi, molds, bacteria, and insect eggs.¹⁴ Ethylene oxide pasteurization increases shelf life and decreases health risks.¹⁴ An industry magazine reports that "since the spice processor cannot preclude or remove

TABLE 8-7. SUMMARY STATISTICS ON STERILIZATION CHAMBERS AND GASES USED BY 39 PHARMACEUTICAL MANUFACTURERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 82			
Number per facility	2.1	1.4	1 - 6
Chamber volume per facility, m ³ (ft ³)	29.2 (1,031.2)	20.0 (706.3)	0.1 - 147.3 (3.5-5,201.9)
Ethylene oxide use = 416.1 Mg/yr (409.6 tons)			
Use per facility, Mg/yr (tons)	10.7 (10.5)	3.12 (3.07)	<0.05 -129.1 (<0.05-127.1)
Total gas use = 830.4 Mg/yr (817.3 tons)			
Use per facility, Mg/yr (tons)	21.3 (21.0)	28.1 (27.7)	0.06 - 92.2 (0.06 - 90.7)

microorganisms from spices, the only means to control microorganisms are: (1) to maintain low moisture content to hinder growth and activity and (2) to treat spices with EO."¹⁵

Several substitutes within the spice industry are available for EO, each of which has disadvantages. Heat sterilization is useful on only a small number of spices, because it lightens or darkens spice color and can cause a 15-percent loss in spice strength by volatilizing spice oils. Neither ionizing radiation nor ethylene imine are approved by the FDA, and their effectiveness is not known. The use of propylene oxide is restricted by the FDA to starches, gums, processed spices, cocoa, and processed nut meats.¹⁴ However, propylene oxide must be heated to be as effective as EO. Using heat restricts its use to a small number of spices because heat volatilizes oils in spices, affecting their quality. Without heat, propylene oxide has one-tenth the microbial killing activity of EO. Finally, propylene oxide requires 16 to 48 hours of exposure time, compared to 6 to 8 hours for EO.

According to an industry source, radiation treatment is a promising alternative to EO fumigation, having several advantages over EO.¹⁶ First, although EO kills a high percentage of bacteria, radiation kills all bacteria. Second, EO requires high humidity and a vacuum, while radiation treatment can be done under ambient conditions. Third, EO leaves a residue in all foods that have been treated, but radiation leaves no residues of any kind.

According to the Census Bureau, SIC 2099 had 1,976 firms in 1982.¹⁷ As shown in Table 8-8, the value of shipments for SIC 2099 increased steadily from \$3.6 billion in 1972 to \$11.0 billion in 1982, a nominal growth of 201 percent over the 10-year period. Value added also increased steadily over the same period rising from \$1.8 billion in 1972 to \$5.7 billion in 1982. Employment experienced two low periods, one in the mid-1970's and another in the early 1980's. The number of production workers declined in 1975 and again in 1979 and 1980, while total employment declined in 1979 and 1981. Both employment measures

TABLE 8-8. RECENT PERFORMANCE DATA FOR SPICE MANUFACTURERS (SIC 2099)

		1972	1975	1977	1978	1979	1980	1981	1982
Product data									
Value of shipments	(10 ⁶ \$)	3,647.9	5,583.8	6,531.0	7,360.6	7,568.9	8,536.5	9,598.9	10,979.3
Industry data									
Total employment	(10 ³ people)	66.2	64.3	71.5	76.8	71.8	73.4	72.8	81.4
Production workers	(10 ³ people)	44.7	44.2	50.9	55.8	52.3	51.7	52.3	57.9
Capital expenditures	(10 ⁶ \$)	91.8	171.3	166.2	199.6	236.0	285.0	208.0	295.4
Value added	10 ⁶ \$)	1,805.2	2,431.3	3,028.1	3,487.8	3,493.8	4,038.0	4,569.6	5,663.3

increased from 1981 to 1982. Capital expenditures increased from \$91.8 million in 1972 to \$295.4 million in 1982 with declining years in 1977 and 1981.

In 1987, the industry definition of SIC 2099 changed. Although spice manufacturers are still included under the new definition, industry figures for 1987 cannot be compared with previous years. Table 8-9 presents the 1987 data for SIC 2099.

The spice and seasoning industry relies heavily on foreign trade. According to one estimate, two-thirds of the spices consumed in the United States are imported.¹⁸ This estimate includes some dehydrated vegetables that are used as seasonings but are not included in the FDA definition of spices.

The 23 firms in the spice manufacturers group that use EO sterilization are distributed evenly across the country, except for a large concentration of seven firms in California.^{10,13} Table 8-10 shows some summary statistics on the sterilization chambers and sterilant gas used by these manufacturers.¹ The 23 facilities operated a total of 27 sterilization chambers in 1986, an average of only 1.2 per facility. The number of chambers per facility ranged from one to four. Average chamber volume per facility was 33.1 m³ (1,168.9 ft³), which is considerably lower than the average for medical device suppliers of 40.1 m³ (1,416.1 ft³). In addition, the range of chamber volumes per facility, 0.1 m³ to 177 m³ (3.5 ft³ to 6,250 ft³), was narrower for the spice manufacturers. Both average chamber volume per facility and the range of chamber volumes per facility for the spices group were roughly equal to the average range for the pharmaceuticals group. Table 8-10 presents the 1987 data for SIC 2099.

The spice manufacturers used 124 Mg (122 tons) of EO and 287 Mg (282 tons) of total gas during 1986. Annual EO use per facility averaged 5.4 Mg (5.3 tons), while total gas use per facility averaged 12.5 Mg (12.3 tons). Average total gas use per facility is roughly equal to average total gas use for the pharmaceuticals group, but average EO use per facility is about half the average for pharmaceutical manufacturers. The inert-gas

TABLE 8-9. 1987 PERFORMANCE DATA FOR SPICE MANUFACTURES
(SIC 2099)

Product data	1987
Value of shipments (10^6 \$)	9,815.8
Industry data	
Total employment (10^3 people)	58.1
Production workers (10^3 people)	40.9
Capital expenditures (10^6 \$)	248.0
Value added (10^6 \$)	5,201.1

**TABLE 8-10. SUMMARY STATISTICS ON STERILIZATION CHAMBERS
AND GASES USED BY 23 SPICE MANUFACTURERS, 1988**

	Average	Standard deviation	Range
Sterilization chambers = 27			
Number per facility	1.2	0.6	1 - 4
Chamber volume per facility, m ³ (ft ³)	33.1 (1,168.9)	14.3 (499.4)	0.1 - 177.0 (3.5 - 6,250.7)
Ethylene oxide use = 124.0 Mg/yr (122.0 tons)			
Use per facility, Mg/yr (tons)	5.4 (5.3)	11.2 (11.0)	<0.05 - 40.0 (<0.05-39.4)
Total gas use = 286.6 Mg/yr (282.1 tons)			
Use per facility, Mg/yr (tons)	12.5 (12.0)	14.0 (13.8)	<0.05 - 56.3 (<0.05 - 55.4)

ratio for the spice manufacturers is 1.31, which is comparable to the 2.88 ratio for the medical device suppliers.

8.4.2.5 Museums and Libraries. According to the 1982 Census of Services, the United States has 1,909 non-commercial museums and art galleries (SIC 8411).¹⁷ In addition, the country had 31,524 public and private libraries in 1987. The sterilization data base contains data for 11 museums and 2 libraries. Interestingly, 4 of the 13 are in Massachusetts and none are in the Southeast or Northwest.

Museums and libraries fumigate books, documents, and other artifacts with EO chiefly to control insect pests and mold. Museum experts report that EO is "especially valuable for treatment of books and archival documents, furs, textiles, and furniture."¹⁹ However, EO has one significant drawback as an artifact fumigant: it settles in rubber, leather, wood, and other organic materials, making it necessary for EO-fumigated artifacts to be aerated for up to a month before they are safe to handle.^{19,20}

It is recommended that all organic materials be fumigated before they are introduced into a museum or library collection.¹⁹ However, telephone conversations with museum and library conservators who use EO revealed a range of fumigation criteria. Some conservators fumigate all new articles, while others fumigate only those articles that fail a visual inspection or that have suspect backgrounds, such as books that were kept in a damp basement.^{21,22}

Ethylene oxide has several substitutes as a fumigant in museum and library use. One possible substitute is sulfuryl fluoride, marketed under the trademark Vikane™. Sulfuryl fluoride is not absorbed by organic materials and dissipates more quickly than EO.²⁰ Furthermore, the cost of sulfuryl fluoride has generally been comparable to the cost of 12/88, based on retail prices and the recommended doses of each sterilant.¹⁹ Sulfuryl fluoride, however, is toxic at high concentrations. It is also corrosive to metals, making it an unacceptable

alternative for artifacts that contain metal. In particular, it could damage books with staple bindings.²³

Conversion from EO to sulfuryl fluoride would entail some startup costs. Some EO fumigation chambers would require modifications to use sulfuryl fluoride. Because sulfuryl fluoride is corrosive to metals, the vent pipes from the chamber must be stainless steel; installing these new vent pipes would represent a startup capital cost for museums/libraries converting to sulfuryl fluoride use.²³

Sulfuryl fluoride is registered with the U.S. Department of Agriculture as a "restricted" pesticide and, therefore, can only be applied by a certified applicator. Certified applicators must pass a test administered by the U.S. Department of Agriculture. Ethylene oxide is not registered as a restricted pesticide and can, therefore, be applied by anyone.²⁴ The time and effort involved in passing the certified applicator test would represent another startup cost for museums/libraries converting to sulfuryl fluoride. Finally, sulfuryl fluoride is registered for use in fumigation chambers, and presently no regulations control sulfuryl fluoride emissions.²⁴

Other alternatives to EO fumigation include deep freezing, CO₂ fumigation, and vacuum treatment. Several European institutions have tested the freezing method and reported that maintaining -18°C (-0.4°F) for 48 hours kills 100 percent of insect life in all stages of the life cycle. Freezers ranging from 0.9 to 1.1 m³ (31.8 to 40 ft³) in size are most commonly used.¹⁹ The necessary freezing apparatus costs approximately \$3,000 to \$4,000.²² Placing artifacts in a vacuum or fumigating them with carbon dioxide also kills insect life.^{21,25} These three methods, however, do not kill mold and fungi; therefore, they are only partial substitutes for EO.

Table 8-11 provides some summary statistics on the sterilization chambers and sterilant gas used by the 11 museums and two libraries included in this study.¹ Each of these 13 facilities operated one sterilization chamber in 1988. These chambers averaged 2.60 m³ (91.82 ft³) in volume and ranged from

**TABLE 8-11. SUMMARY STATISTICS ON STERILIZATION CHAMBERS
AND GASES USED BY 13 MUSEUMS AND LIBRARIES, 1988**

	Average	Standard deviation	Range
Sterilization chambers = 13			
Number per facility	1.0	0.0	1 - 1
Chamber volume per facility, m ³ (ft ³)	2.6 (91.8)	3.7 (130.7)	0.5 - 13.7 (17.7 - 483.8)
Ethylene oxide use = 0.20 Mg/yr (0.20 tons/yr)			
Use per facility, Mg/yr (tons)	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 - 0.05 (<0.05 - 0.05)
Total gas use = 1.68 Mg/yr (1.65 tons/yr)			
Use per facility, Mg/yr (tons/yr)	0.1 (0.1)	0.1 (0.1)	<0.05 - 0.4 (<0.05-0.4)

0.5 m³ to 13.8 m³ (17.7 ft³ to 487.3 ft³). The average chamber volume per facility for this group is roughly one-twentieth the average chamber volume per facility for the medical device suppliers. Additionally, all of the gas use figures are much lower than are the figures for medical device suppliers.¹

During 1988, the museums and libraries group used a total of 0.20 Mg (0.20 tons) of EO and 1.67 Mg (1.64 tons) of total gas. Medical devices suppliers used over 3,000 times as much EO and over 1,500 times as much total gas as did the museums and libraries group. In addition, gas use per cubic meter of chamber volume was much lower for this group than for any other group. Medical device suppliers used 14 times as much total gas and 22 times as much EO per cubic meter of chamber volume as did the museums and libraries group. Furthermore, this latter group used substantially less EO per cubic meter of chamber volume than any other industry group in this study--12.6 kg/m³/yr (0.78 lb/ft³/yr), while all other industry groups each used over 200 kg/m³/yr (12.5 lb/ft³/yr). The inert-gas ratio for the museums and libraries group was 7.40, which suggests that facilities in this group used 12/88 exclusively.

8.4.2.6 Laboratories. Four of the firms being considered for regulation are commercial laboratory rat and mice breeders, which are classified as SIC Code 2790. Animal breeders use EO to sterilize heat-sensitive plastics, heat- and water-sensitive electronic lab equipment, and prepackaged articles required for breeding. These articles include books, phones, optical equipment, meters, microscopes, and face masks.¹⁴

Some alternatives to EO sterilization for laboratory animal breeding do exist, although each has disadvantages. Pressurized steam damages plastics, electronic equipment, and other heat-/water-sensitive materials. In addition, steam does not permeate prepackaged materials as effectively as EO. Dry heat degrades those heat-sensitive materials that cannot withstand temperatures of 160° to 165°C (320° to 329°F). Another alternative, peracetic acid, is not registered as a pesticide and is considered to be carcinogenic. It is also corrosive to most metals and plastics

and has poor penetrating properties. Glutaraldehyde requires at least 10 hours immersion and cannot be used with prepackaged materials. It poses a recontamination danger from hand manipulations and air and cannot be used for materials that would be damaged by water.¹⁴

Two noncommercial research organizations, SIC Code 8922, have also been identified as operators of sterilization chambers. These firms use EO in the same manner as the lab animal breeders mentioned above but on a somewhat more limited scale. Ethylene oxide alternatives and disadvantages mentioned for animal breeders also apply here.¹⁴

The remaining facilities classified as laboratories are two research and development labs (SIC Code 7391), one medical lab (SIC Code 8071), and one commercial testing lab (SIC Code 7397). These firms are considered together because their sterilization practices are similar. In particular, these facilities investigate whether medical devices can be effectively sterilized and yet still function within the human body. Alternatives to EO for these facilities are limited; EO must be used for heat- and moisture-sensitive medical devices and drugs.¹⁴

Table 8-12 reports some summary statistics on the sterilization chambers and sterilant gas used by the 10 laboratories included in this study.¹ These facilities operated 22 EO sterilization chambers during 1988, an average of 2.2 per facility. The number of chambers per facility ranged from one to five. Average chamber volume per facility was 4.15 m^3 (146.56 ft^3) but varied from 0.05 m^3 to 16.1 m^3 (1.77 ft^3 to 568.57 ft^3) per facility. The laboratories group averaged about the same number of chambers per facility as the medical device suppliers group; however, the laboratories group had a lower average chamber volume per facility than did all other groups (except the museums and libraries group). This comparison suggests that the laboratory group operated smaller chambers than did the other groups (except the museums and libraries group).

The laboratory group used 9.55 Mg (9.40 tons) of EO and 78.1 Mg (76.9 tons) of total gas during 1988. The group average

TABLE 8-12. SUMMARY STATISTICS ON STERILIZATION CHAMBERS
AND GASES USED BY 10 LABORATORIES, 1988

	Average	Standard deviation	Range
Sterilization chambers = 22			
Number per facility	2.2	1.6	1 - 5
Chamber volume per facility, m ³ (ft ³)	4.15 (146.56)	4.81 (169.86)	0.5 - 16.1 (17.66-568.57)
Ethylene oxide use = 0.20 Mg/yr (0.20 tons)			
Use per facility, Mg/yr (tons/yr)	0.96 (0.91)	2.57 (2.53)	<0.05 - 8.68 (<0.05 - 8.54)
Total gas use = 1.68 Mg/yr (1.658 tons/yr)			
Use per facility, Mg/yr (tons/yr)	7.8 (7.7)	21.5 (21.2)	<0.05 - 72.3 (<0.05 - 71.2)

of 0.96 Mg (0.94 tons) of EO per facility is roughly equal to the spice manufacturer's use per facility but less than all other groups, excluding museums and libraries. The laboratories also used less total gas per facility, 7.8 Mg/yr (7.7 tons/yr), than did all other groups excluding museums and libraries. The inert gas ratio for laboratories was 7.17.

8.4.2.7 Contract Sterilizers. As mentioned earlier, a subset of sterilization facilities sterilize products on a contract basis. These contract facilities are normally classified under SIC Code 7399 (business services, not elsewhere classified). However, depending on the main type of product sterilized, the facility may fall under another related category. For example, one contract sterilizer works with surgical garments and is classified under SIC Code 7218 (industrial launderers). In addition to the facilities whose primary function is contract sterilization, several facilities that sometimes accept contract work are classified under a different category. These are especially prevalent within the medical device industry.

Reports vary as to the number of contract sterilizers in the United States. One official at the FDA estimated that there are 100 to 125 contract sterilizers of all types (i.e., EO, steam, radiation, etc.). Of these, approximately 60 are EO sterilizers.²⁶ Another source at the FDA estimated that there are 65 contract sterilizers of medical devices, 18 of which do contract work only.²⁷ Only 17 of the 188 facilities in this study have been identified as contract sterilizers exclusively; however, an undetermined number of the other facilities also accept contract work.

The price for contract sterilization varies with the type of sterilization performed. The prices for EO contract sterilization are calculated based on the time the product remains in the chambers (length of cycle) and the amount of gas used. The pressure chambers contain a limited amount of space, and the cost to the sterilization firm is the same whether the chamber is completely full or not. Thus, the price per cubic

foot of product sterilized also varies depending on how full the chamber is.

Some contract sterilizers said in telephone conversations that the articles they processed tended to be of awkward shapes and sizes, limiting the number of articles in the sterilization chambers. Other firms processed smaller and denser loads. The prices quoted were those for full chambers and averaged about \$0.04 per-cubic meter (\$1.30 per-cubic foot).²⁸

Typically, sterilizing with 12/88 is more expensive than sterilizing with pure EO. The difference in price between sterilizing with pure EO and with 12/88 is due to the increased amount of gas necessary to sterilize with 12/88.² In spite of the higher cost, facilities have used the 12/88 formulation because some products or packaging cannot withstand sterilization with pure EO, as was noted previously. In addition, pure EO is explosive, making worker safety a concern. (Note: However, during the early 1990's many facilities are switching to pure EO because of chlorofluorocarbon (CFC) phase-out regulations.)

One expert on sterilization predicted 30 percent growth in the late 1980's and early 1990's for contract sterilizers.² Growth would then continue at a rate of 4 to 5 percent annually. Implicit in this projection is the assumption of no additional Federal regulations in the future. Any new regulations would probably augment the positive growth of contract sterilization, because smaller facilities might cease in-house sterilization operations and begin sending products offsite. [See Section 8.2.1 for further discussion of the possible substitution of contract sterilization for in-house sterilization due to the candidate NESHAP controls on EO emissions.] Indeed, this is already occurring because of CFC regulations.

Table 8-13 contains some summary statistics on the sterilization chambers and sterilant gas used by the 17 contract sterilizers included in this study.¹ These 17 facilities operated 62 EO sterilization chambers in 1988--an average of 3.6 per facility, which is more than any other group in the study. The contract sterilizers also had more chamber volume than any

TABLE 8-13. SUMMARY STATISTICS ON STERILIZATION CHAMBERS
AND GASES USED BY 17 CONTRACT STERILIZERS, 1988

	Average	Standard deviation	Range
Sterilization chambers = 62			
Number per facility	3.6	2.8	1 - 10
Chamber volume per facility, m ³ (ft ³)	87.1 (3,075.9)	72.6 (2,563.8)	13.8 - 277.5 (487.3 - 9,799.8)
Ethylene oxide use = 336.9 Mg/yr (331.6 tons)			
Use per facility, Mg/yr (tons)	19.8 (19.5)	13.0 (12.8)	1.5 - 97.7 (1.5 - 96.2)
Total gas use = 1,567.6 Mg/yr (1,542.9 tons/yr)			
Use per facility, Mg/yr (tons/yr)	92.2 (90.7)	95.8 (94.3)	10.6 - 359.4 (10.4 - 353.7)

other group, averaging 87.1 m³ (3,083.0 ft³) per facility. During 1986, the contract sterilizers used 337 Mg (332 tons) of EO and 1,568 Mg (1,543 tons) of total gas--somewhat more than half the amounts used by the medical device suppliers. However, the contract sterilizers used much more EO and total gas than any other group on a per-facility basis. The inert-gas ratio for contract sterilizers was 3.65, indicating that contract sterilizers fall in the middle of the industry groups regarding their reliance on pure EO. This is not surprising because contract sterilizers service diverse industries with varying sterilization requirements.

8.5 DEMAND FOR ETHYLENE OXIDE STERILIZATION SERVICES

The demanders of EO sterilization services are the facilities that produce (or, in the case of museums and libraries, acquire) the goods that require sterilization. The demand for sterilization arises because sterilization is necessary to ensure the ultimate safety and effectiveness of the object sterilized. Specifically, many products cannot be marketed unless they meet FDA sterilization standards. Medical device suppliers sterilize their products because inadequately sterilized products could cause harmful health effects for users of the devices. Similarly, spice manufacturers sterilize their products because they may otherwise be damaged or contaminated by insects, molds, or bacteria.

The demanders can be separated into two groups. One group demands sterilization of the products they produce and also satisfies their own demand by sterilizing the products in-house. These are the facilities profiled in Sections 8.4.2.1 through 8.4.2.6. The other group of facilities demanding EO sterilization satisfies their demand by using the services of contract sterilizers. We assume that these demanders are facilities in the same industry groups as the facilities that perform in-house EO sterilization. Rather than sterilize their own goods in-house, however, they demand the services of a contract sterilizer.

The market for sterilization services may be viewed as being in equilibrium in the absence of an air emission standard. Demanders of sterilization compare the costs of sterilizing products in-house with the costs of sending their products offsite to a contract sterilizer. Likewise, they compare the costs of the various types of sterilization that can be employed with their products. They select the sterilization technique that minimizes the cost of producing their good or service, including the cost of sterilization. Imposing an air emission standard on EO sterilizers will increase the cost of this type of sterilization relative to other types. It will also increase the cost of producing goods requiring sterilization. The following section analyzes the impact of this relative increase in costs.

8.6 ECONOMIC EFFECTS OF CANDIDATE NESHAP CONTROLS UNDER THREE CONTROL OPTIONS

This section analyzes the economic effects that the candidate NESHAP controls will have on sterilization facilities under three control options.²⁹ As discussed above, EO has been designated a probable human carcinogen, so EPA has developed three possible control options representing increasing levels of stringency. Imposing controls on EO sterilization will increase the cost of performing this type of sterilization. This increase in sterilization costs will, in turn, increase the cost of producing goods and services in the industry groups that demand sterilization.

In the following sections, the provisions of the three control options are summarized. Then, the theoretical framework for analyzing economic impacts that increase production costs are described. Next, the analytical procedure used to evaluate the impacts of the control options is described, and the empirical results of the analysis are presented.

8.6.1 The Three Control Options

The three control options assessed in this analysis represent increasing levels of stringency of control:

1. Option 1 controls only emissions from the chamber vent and the vacuum pump drain;

2. Option 2 controls these two sources of emissions, plus emissions from the aeration room; and

3. Option 3 controls emissions from the main chamber vent, the vacuum pump drain, the aeration room, and the rear chamber exhaust.

8.6.2 Theoretical Framework for Economic Impact Analysis

The ideal procedures for estimating the economic effects of the proposed NESHAP controls use a framework based on the supply and demand for goods or services in the regulated market. [For a detailed description of this framework, see Chapter 2 in Reference 29.] A market demand curve describes the maximum quantity (per period) of a commodity, Q , that individuals or firms are willing to purchase at various prices, ceterus paribus (all else equal). As shown in Figure 8-1, demand curves slope downward, indicating that consumers are willing to buy more of Q at lower prices than at higher prices. This assumes that all other factors that might influence demand--for example, income, prices of related goods, and tastes or preferences--do not change.

If the market process establishes a price of P_1 , consumers will purchase Q_1 of the commodity for a total expenditure equal to OP_1BQ_1 . Because a demand curve measures maximum willingness to pay for each unit of a commodity, the total willingness to pay for Q_1 is the entire area $OABQ_1$ --total expenditures plus the triangle P_1AB . This triangle, which is the difference between what consumers actually pay and the amount they are willing to pay, is known as consumer surplus. It is a good empirical approximation of the dollar value of the well-being consumers receive from consuming a commodity, over and above what they pay for the commodity.

The other principal construct in our conceptual framework is a market supply curve. A supply curve shows the maximum output (per time period) of a commodity that firms are willing to supply at various prices, ceterus paribus. The upward slope of supply curves (as shown in Figure 8-2) indicates that firms are willing to produce more at higher prices than at lower prices, assuming

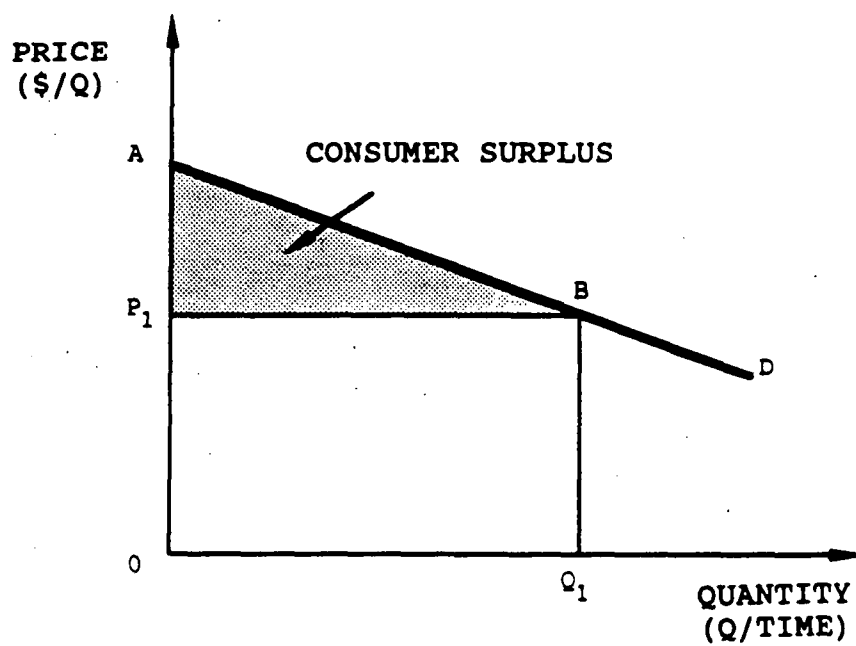


Figure 8-1. Demand curve for Commodity Q.

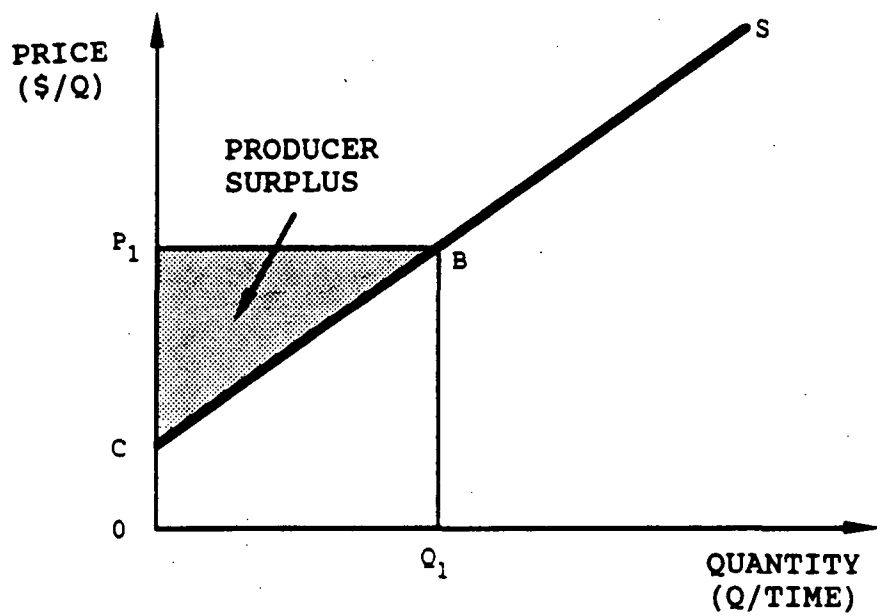


Figure 8-2. Supply curve for Commodity Q.

that other factors influencing the supply curve--prices of inputs (such as labor, energy, and machinery) and production technology--do not change.

If the market process establishes a price of P_1 , then suppliers will produce Q_1 units of the commodity, receiving OP_1BQ_1 in total revenues. However, the cost of producing these Q_1 units is represented by the area $OCBQ_1$. The triangle CP_1B , which is known as producer surplus, is the difference between the minimum amount firms would accept for the Q_1 units and the actual amount they receive for these units. Producer surplus is a good empirical approximation of the dollar value of the returns that firms experience from producing a commodity, over and above the costs of production.

Installing and operating controls on EO emissions from sterilization chambers will increase the cost of sterilization. In a demand-supply framework, this additional cost is represented by an upward shift in the supply curve (from S_1 to S_2 in Figure 8-3). This upward shift in the supply curve leads to a higher market price (P_2) and a smaller quantity demanded (Q_2). The changes in price (from P_1 to P_2) and quantity (from Q_1 to Q_2) are market adjustments attributable to the emissions controls.

The cost of this change in market-clearing price and quantity due to the emissions controls is represented by the area $CDEB$ --the area between the two supply curves S_1 and S_2 and under the demand curve. This area, which constitutes the cost that society experiences because of the emissions controls, equals the sum of the additional cost of producing Q_2 units of the commodity (area $CDEF$) plus the foregone consumer and producer surplus ($Q_1 - Q_2$) on the units of the commodity that are no longer produced or consumed (area EFB). Equivalently, the social cost of emissions controls can be determined by aggregating the impact of the controls on the well-being of consumers and producers of affected commodities. In other words, social cost equals the sum of the change in consumer and producer surplus as a result of the price and quantity adjustments.

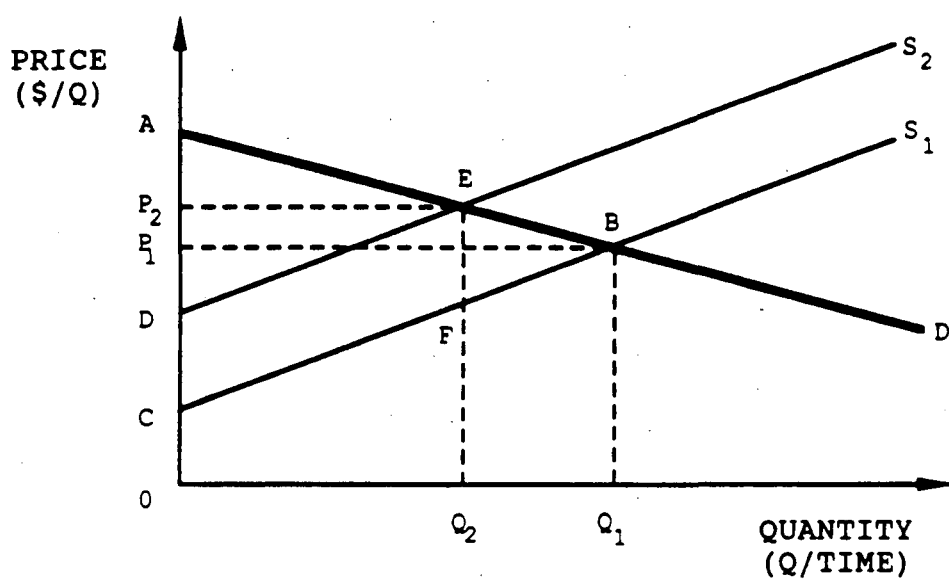


Figure 8-3. Market equilibrium with and without an upward shift in the supply curve due to ethylene oxide emissions controls.

S_1 shows market supply without EO emissions controls.

S_2 shows market supply with emissions controls.

The simple model in Figure 8-3 ignores two potentially important aspects of the economic impact of the candidate NESHAP control under the three control options. First, the controls will apply both to existing and new plants (when they are constructed) that produce sterilized products. Thus, two supply curves are relevant: a supply curve from existing plants and a supply curve from new plants. The candidate NESHAP controls will shift both of these supply curves upward, although the magnitude of these shifts will probably differ. The potential effects of the candidate NESHAP controls on new facilities are addressed in Section 8.8.2.

Second, this discussion implies that all EO sterilization is offered in a market. In fact, much EO sterilization is performed in-house. In this case, the facility's demand for sterilization services is met by its own supply of sterilization services. These facilities do not generally offer to sterilize products for others on a contract basis, so their services are not part of market supply and have no market price. Only the EO sterilization performed on a contract basis is actually marketed. Therefore, employing the supply and demand framework to analyze the impacts of the regulation is not possible. Rather, because most sterilization takes place in the context of producing some other good or service, the impact of the regulation on the production of those goods and services has been analyzed.

As noted above, imposing air emission controls on EO sterilization increases the cost of sterilization, which in turn increases the cost of producing goods requiring sterilization. The candidate NESHAP controls will probably cause some firms to substitute contract sterilization for in-house sterilization. If the candidate NESHAP controls are promulgated, facilities currently sterilizing in-house using EO will face four possible alternatives:

1. Adopt the candidate controls;
2. Switch to another sterilization process;
3. Discontinue in-house sterilization, switching to contract sterilization; or

4. Discontinue sterilizing or producing the sterilized product.

Undoubtedly, substituting contract sterilization for in-house sterilization (Alternative 3) will be the least-cost alternative for some facilities. Others may choose to switch to another method of sterilization. Finally, some facilities may decide to discontinue sterilization or to stop producing products that require sterilization. Because of a lack of necessary data, no attempts are made to decide which facilities will respond in which way to the candidate NESHAP. [For a detailed explanation of the substitution effect, see Section 8.7.4.]

Contract sterilizers' costs will also be increased by imposing the control options. Their choices of possible responses are limited to three alternatives:

1. Adopt the candidate controls;
2. Switch to another sterilization process; or
3. Discontinue sterilization.

8.6.3 Analytical Procedure

The theoretical framework for analyzing economic impacts involves estimating changes in the market price and quantity sold of a product or service. As noted above, however, in-house sterilization is not marketed. Consequently, using the supply and demand framework to analyze the economic effects of the candidate commercial sterilization NESHAP is not possible. As an alternative, EO sterilization is analyzed within the context of the production of the goods and services requiring sterilization and a more qualitative approach is used that approximates the ideal approach.

This approach has four parts. First, dividing commercial sterilizers into seven industry groups imposes some homogeneity on the facilities. Second, each facility's chamber volume and annual EO use is used as proxies for the quantity of sterilized goods produced. By dividing these proxies into the annual compliance cost under the three control options, rough estimates are obtained of the per-unit production cost increase caused by the candidate NESHAP. Third, for each control option, dividing

each facility's annual compliance cost by its total baseline cost of sterilization produces an upper-bound for the percentage increase in production cost caused by the NESHAP under each control option. Finally, dividing each facility's annual compliance cost under each control option by its total sales produces a lower-bound estimate of the percentage production cost increase. Each facility's actual percentage production cost increase attributable to the candidate NESHAP under each control option lies somewhere between its upper- and lower-bound estimates.

8.6.3.1 Industry Grouping. The 188 affected facilities were divided into seven industry groups based on their SIC Code: medical device suppliers, other health-related manufacturers, pharmaceuticals manufacturers, spice manufacturers, museums and libraries, laboratories, and contract sterilizers. The firms within each of these subgroups produce a more homogeneous mix of goods than does the aggregate group. Nevertheless, the product mix is still quite diverse within the industry groups, as is demonstrated in Section 8.1.

8.6.3.2 Chamber Volume as an Output Measure. The sum of the volumes of all sterilization chambers at a facility is one measure of the facility's sterilization capacity. If sterilization cycles for all sizes and types of chambers are of equal duration, then a facility with twice the chamber volume of another facility also have twice the sterilization capacity. If this assumption is not true, then the direct relationship will not hold. For example, if larger chambers undergo longer cycles, then chamber volume will overstate sterilization capacity for large chambers and understate capacity for small chambers. If small chambers undergo longer cycles, then the reverse will hold.

Chamber volume can be used not only as a measure of capacity but also as a measure of output under the following two additional assumptions.

1. All facilities within an industry group perform about the same number of sterilization cycles per year; and

2. The sterilization chambers are always filled with products to approximately the same level.

Under these assumptions, chamber volume would be highly correlated with the volume of goods sterilized.

How valid are these two assumptions? Data from the EPA commercial sterilization data base indicates that facilities do not perform equal numbers of sterilization cycles per chamber, even within industry groups.¹ These data indicate that the first assumption is not true. Therefore, chamber volume may be a poor output measure.

8.6.3.3 EO Use as a Measure of Output. Ethylene oxide use is the second surrogate output measure. The EPA commercial sterilization data base provides data on the amount of EO used per facility during 1986 (1988 or 1985 for some facilities).¹ Ethylene oxide use is a better output measure than chamber volume because EO use varies directly with the volume of goods sterilized, even if firms do not run a consistent number of sterilization cycles per chamber. However, using EO as a measure of the volume of products sterilized requires making the following two assumptions:

1. The concentration of EO per unit of chamber volume is roughly the same for all chambers; and
2. Sterilization chambers are filled with products to roughly the same level for each cycle.

Again, the assumptions necessary for EO use to be a valid measure of output are probably not met. First, the concentration of EO per unit of chamber volume varies depending on the type of gas mixture used. Sterilization with pure EO requires a lower concentration of EO than does sterilization using 12/88. Also, although we have no supporting data, we can speculate that sterilization chambers may not always be filled with products to the same level. Probably facilities running frequent sterilization cycles would always fill their chambers to capacity to minimize costs. However, facilities that sterilize infrequently may run some cycles at less than capacity because they face sporadic orders for sterilized goods and shipment

deadlines. To the extent that this occurs, EO use may overstate the volume of goods sterilized by small-volume sterilizers. If so, this overstatement of facilities' output would make the industry supply curve appear flatter (i.e., more price-elastic) than it actually is.

To this point, a potentially important problem with the output measures has been ignored. As mentioned above, many types of products are sterilized with EO. Chamber volume and EO use are measures of the physical volume of products sterilized, but with such a diverse group of products, volume is not an appropriate measure of output. For example, one facility may sterilize pacemakers while another sterilizes scalpels. Output (in physical or monetary units) per cubic meter of chamber volume will likely differ substantially between pacemakers and scalpels. A similar conclusion seems reasonable regarding EO use as an output measure. In summary, the diversity of products sterilized in the seven industry groups undermines the usefulness of chamber volume and EO use as proxies for facility output.

In addition to measures of total annualized compliance cost (TAC) per unit of output, approximated by the measures described above, two measures are computed that approximate TAC as a percentage of the total baseline cost of producing sterilized products. Ideally, TAC would be reported as a percentage of the total cost of producing sterilized products. However, no data on such costs at the affected facilities are available. Therefore, TAC is reported as a percentage of the total annualized baseline cost of sterilization at a facility (TAC/C) and TAC as a percentage of total facility sales (TAC/S). Because the total cost of producing sterilized products (hereafter referred to as total production cost) equals or exceeds the sterilization cost for any facility, TAC/C is an upper bound for TAC/total production cost. Conversely, total production cost is generally less than or equal to facility sales, particularly because most affected facilities produce a mix of sterilized and unsterilized products. Therefore, TAC/S is a lower bound for TAC/total production cost. The denominators of these two measures,

baseline sterilization costs and facility sales, are described in the following two sections.

8.6.3.4 Baseline Cost of Sterilization. The total annual costs of sterilization for each facility were calculated using a model chamber approach. Specifically, the capital cost and operating cost per cycle are calculated for representative size chambers in the following chamber categories: 12/88, pure EO, nonflammable EO/CO₂, and flammable EO/CO₂. Four representative chamber sizes for the 12/88 gas type were chosen, four for pure EO, three for flammable EO/CO₂, and two for nonflammable EO/CO₂. Representative chamber sizes were selected by first minimizing the total variance between the representative chamber sizes and the sizes of chambers currently in use, as reported in the EPA commercial sterilization data base. Then the selection of representative chamber sizes was finalized by reviewing scatter plots of actual chamber sizes and talking with a vendor of sterilization chambers.

A sterilization chamber vendor provided estimates of capital and operating costs for each model chamber. Capital costs include the cost of the sterilization chamber, the cost of installing the chamber, and the cost of explosion protection equipment for use with flammable sterilant gases. Chamber operating costs include labor, electricity, and sterilant gas costs.

After determining the capital and operating costs for the model chambers, the chambers were divided at the affected facilities into the four gas types outlined above. The operating cost per cycle and capital cost for each chamber were determined by interpolating between the model chambers based on chamber size. Multiplying the operating cost per cycle by the annual number of cycles for the chamber, as reported in the EPA commercial sterilization data base, produced the annual operating cost of the chamber. The capital cost was annualized using a useful life of 10 years and an interest rate of 10 percent, and the annualized capital cost and the annual operating cost were added to obtain the annual sterilization cost for the chamber.

Next, determining the annual baseline cost of sterilization at the facility involved aggregating the annual sterilization costs for individual chambers at each facility. Then, for facilities with controls in place at baseline, the annualized cost of these controls was added. Finally, because the compliance costs are given in last quarter 1987 dollars, the Producers' Price Indices were used for all commodities for 1986 and 1987 to adjust the baseline facility costs from 1986 dollars to 1987 dollars. The costs, therefore, represent 1986 data in 1987 prices.¹⁷

8.6.3.5 Facility Sales. Total facility sales provide an upper-bound estimate of the total costs of producing sterilized goods for several reasons. First, total sales for a facility include sales of sterilized and unsterilized products. For facilities that sterilize only a small portion of output, total sales may substantially exceed sales of sterilized products. Second, sales reflect the price of final products multiplied by the output of these products. They do not directly measure production costs. In general, sales equal production costs plus producer surplus. Producer surplus is only zero when the supply curve is horizontal or the firm is the marginal firm in its industry; therefore, using sales to measure production costs implies one of these two conditions. If producer surplus is not zero, then total sales will overstate total production costs.

As noted, sales are reported on a facility-specific basis. When a facility did not report its own sales and the parent company sales were available, the amount of sales per employee for the parent company was multiplied by the number of employees at the facility. This calculation assumes that the amount of sales per employee at the parent company and the facility are the same, which would not be true, for example, if the facility were more capital-intensive than the parent company. No information regarding the validity of this assumption is available.

Where neither sales nor employment information was available, estimating facility sales was accomplished by using an ordinary least-squares regression of facility sales on facility EO use. Dummy variables were included to represent the seven

industry groups, and a log-log functional form was used. As with baseline annual sterilization costs, facility sales were adjusted from 1986 dollars to 1987 dollars, using the Producers' Price Indices for all commodities for 1986 and 1987.¹⁷

8.6.4 Results

As explained in the previous section, the economic analysis was based on the annual cost of complying with the candidate NESHAP controls under each of three control options. The three control options represent increasing levels of stringency of control, as described in Section 8.6.1. The control costs under each control option are evaluated relative to chamber volume, EO use, total baseline sterilization costs, and total facility sales. The summary statistics on these values are presented in this section.

8.6.4.1 Total Annualized Cost (TAC). Total annualized cost measures the annual engineering cost of compliance with the candidate NESHAP controls under each of the three control options, as described in Chapter 7 of the Background Information Document. Total annualized cost under Option 1 equals the capital cost of an acid water scrubber and other necessary hardware annualized over a 10-year period at an interest rate of 10 percent, plus annual operating costs for the scrubber, including labor, materials, and ethylene glycol disposal costs. Electric and water costs for scrubber operation were assumed to be insignificant and are not included. Emissions from the vacuum pump drain were assumed to be controlled using a water-sealed vacuum pump(s) with closed-loop recirculation and a liquid-gas separator. Costs for these were estimated, as were costs for the piping for manifolding the chambers at a facility to the existing control device or to a scrubber.³⁰

The total annualized compliance costs under Option 2 include the costs described under Option 1 plus the additional costs of controlling the emissions from the chamber in which the product is aerated. For the cost analysis, it was assumed that a facility could use insulated shipping containers as modular aeration units, replacing all existing aeration processes

conducted in aeration rooms over 84 cubic meters. For these facilities, the number of modular units needed was estimated as were the costs for purchasing and installing these units. Costs were assessed for both catalytic oxidation units and gas/solid reactant systems that might be used to control the emissions, for any manifolding required, and for materials, labor, and other operating costs. The least costly approach, a gas/solid reactant system, was selected for the impact analysis.³¹

Finally, the total annualized compliance cost under Option 3 includes the compliance costs under Option 2 plus, for those facilities with rear chamber exhausts on some or all of their chambers, the costs of controlling the emissions from that source. Facilities with total sterilizer volumes less than 7 m³ probably do not have rear chamber exhausts and therefore were not included in this cost analysis.³² Several control methods were considered for rear chamber exhaust emissions, including installing dedicated scrubbers and manifolding the rear chamber exhaust emissions to the aeration room control. This impact analysis used the least costly method, the dedicated add-on scrubbers.

Table 8-14 reports the median and range of TAC per facility for each of the seven industry groups under each control option and includes only facilities incurring positive total annual compliance costs. As shown in Table 8-15, under Option 1, 29 facilities do not incur compliance costs. Under Option 2, only two facilities escape compliance costs, and under Option 3, all facilities but one incur at least some compliance cost.

Under Option 1, the median TAC's range from \$8,400 to \$44,000. The highest median TAC, \$44,000, is incurred by contract sterilizers. Spice manufacturers experience the second highest median TAC, \$35,000. Other industries with relatively high TAC's are other health-related manufacturers (median TAC of \$31,900) and medical device suppliers (median TAC of \$28,000).

A medical device supplier incurs the maximum TAC of any facility--\$128,000. Other industry groups having individual

TABLE 8-14. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) UNDER THE THREE CONTROL OPTIONS, FOR AFFECTED INDUSTRY GROUPS^{a b}

Industry group	Option 1		Option 2		Option 3	
	Median, \$10 ³	Range, \$10 ³	Median, \$10 ³	Range, \$10 ³	Median, \$10 ³	Range, \$10 ³
Miscellaneous/laboratories	13.5	8.3 - 38.2	22.8	17.6 - 61.5	22.8	17.6 - 90.4
Spice manufacturers	35.0	8.3 - 71.6	47.1	17.6 - 90.7	65.8	17.6 - 109.6
Pharmaceuticals manufacturers	23.8	2.5 - 106.0	35.2	9.3 - 180.4	52.6	17.6 - 211.1
Other health-related	31.9	8.3 - 75.6	47.1	17.6 - 206.6	65.5	17.6 - 238.4
Medical equipment suppliers	28.0	0.6 - 128.0	38.6	9.3 - 240.0	55.4	17.6 - 271.7
Contract sterilizers	44.0	26.4 - 104.0	63.1	39.4 - 210.0	89.5	58.8 - 240.8
Museums and libraries	8.4	8.3 - 29.5	17.7	17.6 - 38.8	17.7	17.6 - 57.5

^aTotal annual compliance cost is "cumulative" in the sense that the TAC under Option 2 equals the TAC under Option 1 plus the incremental annualized compliance costs associated with Option 2, and the TAC under Option 3 equals the TAC under Option 2 plus the incremental annualized compliance costs associated with Option 3.

^bIncluding only facilities with positive compliance costs: 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. See Table 9-15 for the total number of facilities in each industry group and the number incurring no compliance costs as a result of each control option.

TABLE 8-15. COUNT OF FACILITIES HAVING POSITIVE AND ZERO CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) UNDER THE THREE CONTROL OPTIONS, FOR AFFECTED INDUSTRY GROUPS^a

Industry group	Option 1		Option 2		Option 3	
	TAC=0	TAC > 0	TAC = 0	TAC > 0	TAC = 0	TAC > 0
Miscellaneous/laboratories	0	10	0	10	0	10
Spice manufacturers	4	19	0	23	0	23
Pharmaceuticals manufacturers	3	36	1	38	1	38
Other health-related	3	21	1	23	0	24
Medical equipment suppliers	13	49	0	62	0	62
Contract sterilizers	6	11	0	17	0	17
Museums and libraries	0	13	0	13	0	13

^aTotal annual compliance cost is "cumulative" in the sense that the TAC under Option 2 equals the TAC under Option 1 plus the incremental annualized compliance costs associated with Option 2, and the TAC under Option 3 equals the TAC under Option 2 plus the incremental annualized compliance costs associated with Option 3.

facilities that experience high TAC's include pharmaceutical manufacturers, with a maximum TAC of \$106,000, and contract sterilizers, with a maximum TAC of \$104,000.

At the same time, facilities in six of the seven industry groups do not incur compliance costs under Option 1 (see Table 8-15). These are facilities that already have the required controls in place. Under Option 1, the lowest positive TAC for an affected facility is a medical device supplier, with a TAC of \$600. The lowest TAC for an affected contract sterilizer, on the other hand, is a relatively high \$26,400.

Under Option 2, the median TAC ranges from \$17,700 for museums and libraries to \$63,100 for contract sterilizers. Also experiencing relatively high median TAC under Option 2 are spice manufacturers and other health-related manufacturers, each with a median TAC of \$47,100. Under this control option, the highest TAC facility is again a medical device supplier, with a TAC of \$240,000. Contract sterilizers and other health-related manufacturers also have facilities with TAC's over \$200,000. The lowest cost-controlled facilities, each with a TAC of \$9,300 under Option 2, are found in the pharmaceuticals manufacturers and medical device suppliers groups.

Finally, under Option 3, facilities with a chamber fitted with rear chamber exhausts incur incremental control costs, compared to Option 2. The highest median TAC, again for contract sterilizers, rises to \$89,500. Spice manufacturers and other health-related manufacturers incur a median TAC under Option 3 of \$65,800 and \$65,500, respectively. Museums and libraries, on the other hand, incur a median TAC of only \$17,700 under Option 3. The maximum value for a TAC is incurred by a medical device supplier: \$271,700. Pharmaceuticals manufacturers, other health-related manufacturers, and contract sterilizers also contain facilities that incur a TAC over \$200,000 under Option 3. The highest TAC experienced by a museum or library, on the other hand, is only \$57,500 even under Option 3.

8.6.4.2 TAC Relative to Chamber Volume. Table 8-16 reports the median and range of total annualized costs per cubic meter of

TABLE 8-16. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) PER CUBIC METER OF FACILITY CHAMBER VOLUME, FOR AFFECTED INDUSTRY GROUPS^a

Industry group	Option 1		Option 2		Option 3	
	Median, \$10 ³ /M ³ (\$10 ³ /ft ³)	Range, 10 ³ /M ³ (\$10 ³ /ft ³)	Median, \$10 ³ /M ³ (\$10 ³ /ft ³)	Range, \$10 ³ /M ³ (\$10 ³ /ft ³)	Median, \$10 ³ /M ³ (\$10 ³ /ft ³)	Range, \$10 ³ /M ³ (\$10 ³ /ft ³)
Miscellaneous/laboratories	6.4 (226.0)	2.4 - 293.8 (84.8 - 10,375.5)	10.4 (367.3)	3.8 - 622.2 (134.2 - 21,972.8)	10.4 (367.3)	5.6 - 622.2 (197.8 - 21,972.8)
Spice manufacturers	2.0 (70.6)	0.4 - 97.9 (14.1 - 3,457.3)	2.7 (95.3)	0.2 - 207.4 (7.1 - 7324.2)	3.8 (134.2)	0.5 - 207.4 (17.7 - 7,324.2)
Pharmaceuticals manufacturers	3.0 (105.9)	0.0 - 59.2 (0.0 - 2,090.6)	4.0 (141.3)	0.4 - 124.9 (14.1 - 4,410.8)	5.6 (197.8)	0.7 - 124.9 (24.7 - 4,410.8)
Other health-related	1.8 (63.6)	0.6 - 21.0 (21.2 - 741.6)	2.3 (81.2)	0.2 - 44.4 (7.1 - 1,568.0)	3.0 (105.9)	0.3 - 44.4 (10.5 - 1,568.0)
Medical device suppliers	2.3 (81.2)	0.0 - 297.7 (0.0 - 10,513.2)	2.6 (91.8)	0.1 - 626.1 (3.5 - 22,110.5)	4.1 (144.8)	0.3 - 626.1 (10.5 - 22,100.5)
Contract sterilizers	1.5 (53.0)	0.7 - 2.3 (24.7 - 81.2)	1.6 (56.5)	0.2 - 3.5 (7.1 - 123.6)	1.8 (63.6)	0.3 - 4.3 (10.5 - 151.9)
Museums and libraries	8.2 (289.6)	2.1 - 16.4 (74.2 - 579.2)	17.4 (614.5)	2.8 - 34.7 (98.9 - 1,225.4)	17.4 (614.4)	4.2 - 34.7 (148.3 - 1,225.4)

^aIncluding only facilities with positive compliance costs: 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. Facilities with impact measures of 0.0 percent have positive TAC, but the TAC/CV is less than 0.05 percent.

chamber volume per facility (TAC/CV) under each of the control options. Under all three control options, the highest medians are experienced by the museums and libraries group of facilities, while the laboratories industry group contains the highest single value of TAC/CV. These two industries incur relatively low compliance costs, but they also have extremely low chamber volume. Thus, their TAC/CV is high. Under Option 1, museums and libraries have a median TAC/CV of $\$8,200/\text{m}^3$ ($\$289,581/\text{ft}^3$), while laboratory facilities incur a median TAC/CV of $\$6,400/\text{m}^3$ ($\$2,260,142/\text{ft}^3$). Four of the other five industry groups experience median values for TAC/CV of $\$2,200/\text{m}^3$ ($\$77,692/\text{ft}^3$) or less. The maximum TAC/CV under Option 1 is experienced by a medical device supplier: $\$297,700/\text{m}^3$ ($\$10,513,194/\text{ft}^3$).

Under Options 2 and 3, the median TAC/CV for the museums and libraries group increases to $\$17,400/\text{m}^3$ ($\$614,476/\text{ft}^3$), while the median TAC/CV experienced by the laboratories group is $\$10,400/\text{m}^3$ ($\$367,273/\text{ft}^3$). The highest single TAC/CV is again experienced by a medical device supplier: $\$626,100/\text{m}^3$ ($\$22,107,018/\text{ft}^3$). Finally, under Option 3, the museums and libraries group again experiences a median of $\$17,400$ ($\$614,476/\text{ft}^3$) and the maximum again is $\$626,100$ ($\$22,110,549/\text{ft}^3$), experienced by a medical device supplier.

8.6.4.3 TAC Relative to EO Use. Table 8-17 shows summary statistics for total annualized compliance cost per metric ton of facility EO use (TAC/EO) under each of the three control options. As with TAC/CV, the museums and libraries and the laboratories incur the largest impacts, when measured by TAC/EO. As with TAC/CV, these facilities' relatively low compliance costs combine with extremely low EO use to yield high TAC/EO values. Under Option 1, the median TAC/EO incurred by the museum and library facilities is $\$1,216,100/\text{Mg}$ ($\$1,196,894/\text{ton}$). The median experienced by the laboratories group of facilities is $\$163,100/\text{Mg}$ ($\$160,524/\text{ton}$). The other five industry groups experience much lower median TAC/EO, ranging from $\$8,100/\text{Mg}$ ($\$7,972/\text{ton}$) for contract sterilizers to $\$31,100/\text{Mg}$ ($\$30,609/\text{ton}$) for spice manufacturers. The maximum TAC/EO experienced by any

TABLE 8-17. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) PER METRIC TON OF ETHYLENE OXIDE USED BY FACILITY, FOR AFFECTED INDUSTRY GROUPS^{3, a}

Industry group	Option 1		Option 2		Option 3	
	Median, \$10 ³ /Mg (\$10 ³ /R ³)	Range, 10 ³ /Mg (\$10 ³ /R ³)	Median, \$10 ³ /Mg (\$10 ³ /R ³)	Range, \$10 ³ /Mg (\$10 ³ /R ³)	Median, \$10 ³ /Mg (\$10 ³ /R ³)	Range, \$10 ³ /Mg (\$10 ³ /R ³)
Miscellaneous/laboratories	163.1 (160.5)	4.4 - 3,050.7 (4.3 - 3,002.5)	240.0 (236.2)	7.1 - 6,460.7 (7.0 - 6,358.7)	292.7 (288.1)	10.4 - 6,460.7 (10.2 - 6,358.7)
Spice manufacturers	31.1 (30.6)	7.0 - 2,033.8 (6.9 - 2,001.7)	28.3 (27.9)	1.8 - 4,307.1 (1.8 - 4,239.0)	37.6 (37.0)	2.4 - 4,307.1 (2.4 - 4,239.1)
Pharmaceuticals manufacturers	18.3 (18.0)	0.0 - 1,076.7 (0.0 - 1,059.7)	19.8 (19.5)	1.1 - 2,280.2 (1.1 - 2,244.2)	26.9 (26.5)	1.7 - 2,280.2 (1.7 - 2,244.2)
Other health-related	11.0 (10.8)	0.6 - 3,660.8 (.59 - 3,603.0)	14.3 (14.1)	1.6 - 7,752.8 (1.6 - 7,630.4)	16.8 (16.5)	1.8 - 7,752.8 (1.8 - 7,630.4)
Medical device suppliers	12.4 (8.0)	0.0 - 1,525.3 (0.0 - 1,501.2)	13.2 (13.0)	1.2 - 3,230.3 (1.2 - 3,179.3)	19.5 (19.2)	2.0 - 3,230.3 (2.0 - 3,179.3)
Contract sterilizers	8.1 (8.0)	1.1 - 20.9 (1.1 - 20.6)	6.1 (6.0)	2.0 - 39.1 (2.0 - 38.5)	7.3 (7.2)	2.5 - 54.4 (2.5 - 53.5)
Museums and libraries	1,216.1 (1,196.9)	183.0 - 9,152 (180.1 - 9,007.5)	2,352.8 (2,315.6)	385.5 - 19,382 (379.4 - 19,076.0)	2,352.8 (2,315.6)	38.5 - 19,382 (37.9 - 19,076)

^aIncluding only facilities with positive compliance costs: 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. Facilities with impact measures of 0.0 percent have a positive TAC, but the TAC/EO is less than 0.05 percent.

facility under Option 1 is \$9,152,000/Mg (\$9,007,458/ton), experienced by a museum and library facility. Other industry groups reveal maximum TAC/EO values ranging from \$20,900/Mg (\$20,576/ton) for contract sterilizers to \$3,660,800/Mg (3,604,048/ton) for other health-related manufacturing. The minimum TAC/EO is \$0 for six of the seven industry groups under Option 1 but is \$183,000/Mg (\$180,110/ton) for the museums and libraries group.

Under Options 2 and 3, the same basic pattern is evident. The highest median TAC/EO is experienced by the museums and libraries industry, \$2,352,800/Mg (\$2,315,641/ton) under both control options. The second highest median TAC/EO under Options 2 and 3 is experienced by the laboratories industry group: \$240,000/Mg (\$236,210/ton) under Option 2 and \$292,700/Mg (\$288,077/ton) under Option 3. The maximum TAC/EO value for any facility is experienced by a museum and library facility, \$19,382,000/Mg (\$19,075,890/ton) under both control options. Maximum TAC/EO values for other industry groups range from \$39,100/Mg (\$35,530/ton) for contract sterilizers to \$7,752,800/Mg (\$7,630.356/ton) for other health-related manufacturing groups under Option 2 and from \$54,400/Mg (\$53,541/ton) for contract sterilizers to \$7,752,800/Mg (\$7,630,356/ton) for other health-related manufacturing groups under Option 3.

8.6.4.4 TAC Relative to Baseline Annual Sterilization Cost. Table 8-18 reports the medians and ranges of total annualized compliance cost as a percentage of baseline annual sterilization costs (TAC/C) under the three control options. As mentioned above, TAC/C represents an upper-bound estimate of TAC relative to total production cost, the desired impact measure.

Under Option 1, the median values for TAC/C range from 16.0 percent for medical device suppliers to 48.3 percent for museums and libraries. The second highest median TAC/C for Option 1 is 44.7 percent, experienced by spice manufacturers. The laboratories industry group has a median TAC/C of 27.6 percent, while contract sterilizers have a median TAC/C of

TABLE 8-18. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) AS A PERCENTAGE OF
BASELINE ANNUAL STERILIZATION COSTS, FOR AFFECTED INDUSTRY GROUPS^{a b}

Industry group	Option 1		Option 2		Option 3	
	Median, %	Range, %	Median, %	Range, %	Median, %	Range, %
Miscellaneous/laboratories	27.6	3.2 - 67.4	46.0	5.2 - 101.4	56.0	7.6 - 142.3
Spice manufacturers	44.7	18.8 - 118.1	52.3	1.9 - 144.9	68.4	4.0 - 198.8
Pharmaceuticals manufacturers	20.2	0.4 - 117.2	31.6	2.5 - 166.7	40.1	7.9 - 182.0
Other health related	20.4	1.0 - 45.0	19.1	1.3 - 95.3	25.5	1.1 - 95.3
Medical device suppliers	16.0	0.1 - 83.3	16.6	1.3 - 118.6	24.4	2.0 - 177.8
Contract sterilizers	16.3	4.5 - 78.6	10.9	1.2 - 63.4	13.8	2.0 - 91.8
Museums and libraries	48.3	11.4 - 115.8	100.4	24.1 - 152.4	100.4	24.1 - 225.8

^aBaseline annual sterilization costs include annual operating costs, annualized capital costs, and annualized costs of any emissions controls present at baseline. Baseline costs represent 1986 data adjusted from 1986 dollars to 1987 dollars using the Producers' Price Indices for all commodities for 1986 and 1987.

^bIncluding only facilities with positive compliance costs. This includes 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. Facilities with impact measures of 0.0 percent have a positive TAC, but the TAC/C is less than 0.05 percent.

20.2 percent under Option 1. Other health-related manufacturers have a median TAC/C of 20.4 percent, while contract sterilizers have a median TAC/C of 16.3 percent. Although some facilities in six of the seven industry groups experience no compliance cost under Option 1, other facilities experience TAC/C as high as 118.1 percent. This maximum TAC/C is incurred by a spice manufacturing facility. Other facilities with TAC/C over 100 percent are found in the pharmaceuticals manufacturing industry (maximum TAC/C of 117.2 percent) and museums and libraries (maximum TAC/C of 115.8 percent).

Under Options 2 and 3, the median facility in the museums and libraries industry experiences sterilization costs doubled by the controls (TAC/C of 100.4 percent). The median TAC/C for the other six industry groups ranges from 10.9 percent for contract sterilizers to 52.3 percent for spice manufacturers under Option 2, and from 13.8 percent for contract sterilizers to 68.4 percent for spice manufacturers under Option 3.

The highest TAC/C for any facility under Option 2 is 166.7 percent, experienced by a pharmaceuticals manufacturer. Other high TAC/C facilities are found in the museums and libraries group (152.4 percent) and the spice manufacturing group (144.9 percent). Even in the contract sterilizer industry, one facility experiences a TAC/C of 63.4 percent. Under Option 3, the maximum impacts range from 91.8 percent for contract sterilizers to 225.8 percent for museums and libraries, and four of the seven industry groups have facilities that experience 177 percent TAC/C values, or higher. The lowest TAC/C facilities in six of the seven industry groups incur TAC/C less than 8 percent under Options 2 and 3, but the lowest TAC/C facility in the museums and libraries group has a value of 24.1 percent under both Options 2 and 3.

The relatively low TAC/CV, TAC/EO, and TAC/C for the contract sterilizers under all three control options support the hypothesis that the contract sterilizers may experience economies of scale in controlling EO emissions. In other words, the candidate NESHAP controls may cause lower per-unit increases in

production costs for contract sterilizers than for facilities in the other groups.

8.6.4.5 TAC Relative to Total Facility Sales. Table 8-19 reports the total annualized compliance cost as a percentage of total annual facility sales (TAC/S) under the three control options. As described above, this measure represents the lower-bound estimate of total annualized compliance cost as a percentage of total annual baseline production cost.

Under Option 1, the median TAC/S values range from less than 0.1 percent (for museums and libraries and pharmaceuticals manufacturers) to 2.0 percent for contract sterilizers. The highest TAC/S under Option 1 is experienced by a contract sterilizer: 12.8 percent. Medical equipment suppliers have the next highest maximum TAC/S under Option 1. One medical device supplier experiences a TAC/S of 5.5 percent. The maximum TAC/S for the other industry groups ranges from 1.6 percent, for the other-health-related-and-miscellaneous-and-libraries groups, to 4.2 percent for museums and libraries.

Under Option 2, the contract sterilizers have a median TAC/S of 3.9 percent, while all other industry groups experience median TAC/S values between 0.0 percent and 0.5 percent. The maximum TAC/S incurred under Option 2 is again a contract sterilizer. For this facility, TAC represents 25.9 percent of annual sales under Option 2. The maximum TAC/S values experienced by other industry groups range from 2.3 percent, for other health-related manufacturers, to 8.8 percent, for museums and libraries.

Under Option 3, the median TAC/S for contract sterilizers rises to 4.6 percent. Again, all the other industry groups have median TAC/S values less than one percent. The highest maximum value is again a contract sterilizer, which incurs TAC/S of 29.7 percent. Industry maximums for TAC/S for the other six industry groups range from 3.0 percent to 9.6 percent.

8.7 EFFECTS OF THE REGULATION ON SMALL BUSINESSES

8.7.1 Requirements of the Regulatory Flexibility Act

The Regulatory Flexibility Act requires the awareness and consideration of small entities as regulations are being

TABLE 8-19. CUMULATIVE TOTAL ANNUAL COMPLIANCE COST (TAC) AS A PERCENTAGE OF ANNUAL FACILITY SALES, FOR AFFECTED INDUSTRY GROUPS^{a b d}

Industry group	Option 1		Option 2		Option 3	
	Median, %	Range, %	Median, %	Range, %	Median, %	Range, %
Miscellaneous/laboratories	0.1	0.0 - 1.6	0.2	0.0 - 2.6	0.2	0.0 - 3.8
Spice manufacturers	0.4	0.0 - 2.7	0.5	0.0 - 6.2	0.7	0.0 - 8.0
Pharmaceuticals manufacturers	0.0	0.0 - 3.2	0.1	0.0 - 4.6	0.1	0.0 - 4.6
Other health related	0.2	0.0 - 1.6	0.3	0.0 - 2.3	0.4	0.0 - 3.0
Medical device suppliers	0.1	0.0 - 5.5	0.1	0.0 - 6.9	0.2	0.0 - 9.6
Contract sterilizers	2.0	0.3 - 12.8	3.9	0.3 - 25.9	4.6	0.5 - 29.7
Museums and libraries ^c	0.0	0.0 - 4.2	0.0	0.0 - 8.8	0.0	0.0 - 8.8

^a Facility sales amounts represent 1986 data adjusted from 1986 dollars to 1987 dollars using the Producers' Price Indices for all commodities for the years 1986 and 1987.

^b Some facility sales figures were unavailable and were estimated using parent company sales or a regression of facility sales on EO use.

^c Rather than facility sale, operating budgets were estimated for each facility in this group.

^d Including only facilities with positive compliance costs: 159 facilities under Option 1, 186 facilities under Option 2, and 187 facilities under Option 3. Facilities with impact measures of 0.0 percent have a positive TAC, but the TAC/S is less than 0.05 percent.

developed. The RFA requires a determination of whether there is a "significant economic impact" on a "substantial number" of small entities. The EPA has issued RFA guidelines containing the following criteria for use in determining what is a significant economic impact:

1. Annualized compliance costs increase total cost of production by more than 5 percent;
2. Compliance costs as a percentage of sales for small plants are at least 10 percentage points higher than for large plants;
3. Capital costs of compliance represent a significant portion of capital available to small entities; and
4. The requirements of the regulation are likely to result in closures of small entities.

Normally, a substantial number of small entities are said to incur significant impacts, if at least 20 percent of the small entities experiencing increased costs as a result of the regulation meet the above criteria. However, even if 20 percent of affected small entities meet the above criteria, if that 20 percent represents only a very small absolute number of affected entities, a substantial number of affected small entities do not incur significant impacts.

8.7.2 Small Businesses Performing Ethylene Oxide Sterilization

Because EO sterilization is the major line of business for contract sterilizers, these firms will probably incur relatively large impacts. In the other industry groups, EO sterilization is only one of many operations performed in the course of producing another good or service. For most of these firms, EO sterilization represents a small share of their total production costs. Therefore, firms in these sectors are not expected to incur significant economic impacts. In addition, in many of the other sectors, firms performing EO sterilization are larger than those in the contract sterilizer sector. For these reasons, the contract sterilizer sector's impacts and firm sizes were first examined in detail. Then, small business impacts were considered in the other industry groups.

8.7.3 Small Businesses in the Contract Sterilizer Industry Group

Firms in the contract sterilizer sector are considered small if they have annual sales of less than \$3.5 million. Nine of the 17 facilities included in the contract sterilizer industry group were contacted to obtain information on facility sales and credit availability and cost, to characterize the contract sterilizers' clients, and to investigate the possibility of substituting other sterilization techniques for EO sterilization. Of the nine, eight responded, with one of the eight indicating that it no longer used EO. Additional information about firm sales was obtained from Dun and Bradstreet's "Dun's Market Identifiers."

As expected, many of the contract sterilizers are small. Based on sales information obtained from the facilities or from Dun and Bradstreet where available, and on our sales estimates when no data are available from the other sources, 12 of the remaining 16 facilities in the contract sterilizer sector still performing EO sterilization are small. To estimate the increase in total production costs for these small businesses, baseline sterilization costs were used as a proxy for total production cost. This yields a conservative estimate of the total production cost increase. Under control Option 1, eight of the 12 small businesses are expected to incur compliance costs exceeding 5 percent of baseline sterilization costs. Under control Option 2 and 3, 11 of 12 are expected to incur compliance costs exceeding five percent of baseline sterilization costs.

Initially, therefore, a substantial number of small entities may be significantly affected by the regulation. In talking to the facilities, however, several things were discovered that will mitigate the severity of the impacts. First, some of the facilities contacted indicated that EO sterilization is only a part of their business. Several mentioned that they also offer other types of sterilization and that they are encouraging their customers to substitute these other types for EO wherever possible. Thus, even if the facilities stopped offering EO sterilization, they might not close. Secondly, and potentially more importantly, six of the eight facilities contacted indicated

that if their client industries were also regulated, they expected demand for their services to increase. Their estimates for the increases in their business ranged from 20 percent to 200 percent.

Because of the relatively lower per-unit compliance costs incurred by contract sterilizers, some facilities currently sterilizing in-house will probably choose, as a result of the regulation, to stop sterilizing in-house and substitute contract sterilization. If such a substitution occurs, then both the revenues and the costs of contract sterilizers may increase as a result of the regulation, and revenues may increase by more than costs. The following section discusses substituting contract for in-house sterilization in more detail.

8.7.4 Substitution of Contract Sterilization for In-House Sterilization

As discussed above, EO sterilization is performed in-house by facilities that specialize in producing other goods or services, of which sterilization is a small but necessary part, and by contract sterilizers who specialize in sterilizing goods for other producers. In this analysis, in-house sterilization is performed by medical device suppliers, spice manufacturers, pharmaceuticals manufacturers, other health-related manufacturers, laboratories, and museums and libraries.

The cost of using contract sterilization includes some additional costs not experienced in in-house sterilization. These additional costs include the cost of transporting the products to and from the contract sterilizer, the inventory cost of products while in transit, the reliability and negotiation costs of dealing with an outside supplier, and the cost of products damaged or not properly sterilized. These are referred to as transactions costs. The per-unit cost of actually performing the sterilization is expected to be lower for contract sterilizers because their higher volume enables them to take advantage of economies of scale.

Figure 8-4 shows the market for contract sterilization prior to the regulation. Because in-house sterilization is demanded by

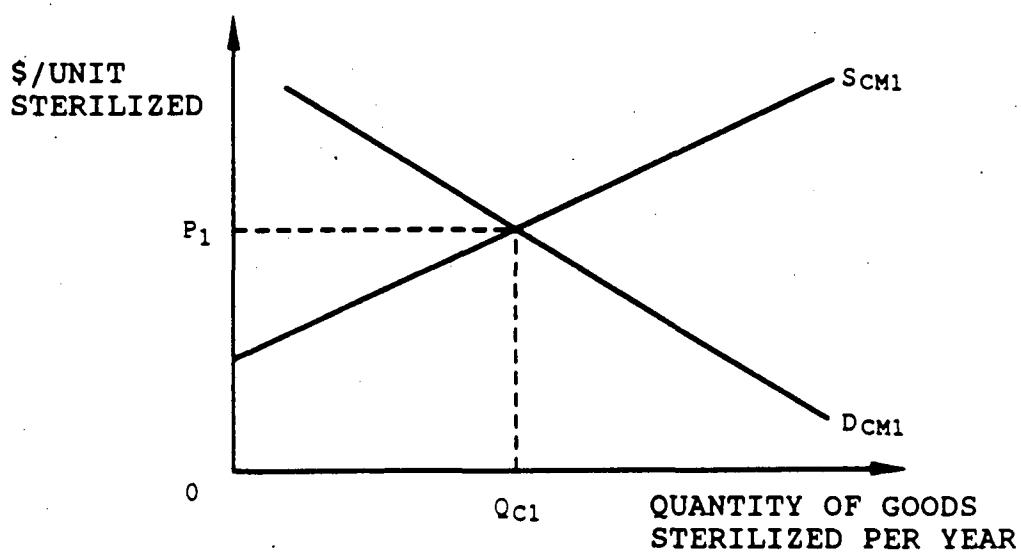


Figure 8-4. The market for contract sterilization without the air emission standard in place.

the same facility that performs it, in-house sterilization services are not marketed, so in-house services have no market price. Facilities that produce goods that need sterilization compare the cost of sterilizing them in-house with the cost of using a contract sterilizer, including the transactions costs described above. Without the air emissions standard in place, the market for contract sterilization services is in equilibrium at a price P_1 . At this price, producers of Q_{C1} goods requiring sterilization have found that the cost of sterilizing them in-house exceeds the cost of using a contract sterilizer, including the transactions costs, and have chosen to substitute contract sterilization for in-house sterilization.

Imposing emissions controls on EO sterilizers will increase the marginal costs of both in-house and contract sterilization. Figure 8-5 shows the effect of the regulation on the sterilization supply curves of a typical contract sterilizer and a typical in-house sterilizer. These supply curves show the relationship between the marginal cost of sterilization and the number of goods sterilized per unit of time. The upward slope indicates that, as more goods are sterilized per unit of time, the cost of sterilizing each additional good (the marginal cost) increases.

Marginal cost curve MC_{C1} shows the contract sterilizer's marginal cost of sterilizing each quantity of goods without the air emission standard in place, while MC_{C2} shows the marginal cost of sterilizing each quantity of goods with the air emission standard in place. The vertical distance between the two curves is the total annual compliance cost per unit sterilized (TAC/unit) for each quantity sterilized. For example, suppose the contract sterilizer sterilizes Q_C quantity of goods. (This quantity is arbitrarily chosen; without information about the market price of contract sterilization, it is not known what quantity of goods the facility sterilizes.) If this sterilizer processes Q_C quantity of goods, the marginal cost of sterilization without the regulation in effect is OA. The marginal cost of sterilization at output level Q_C with the

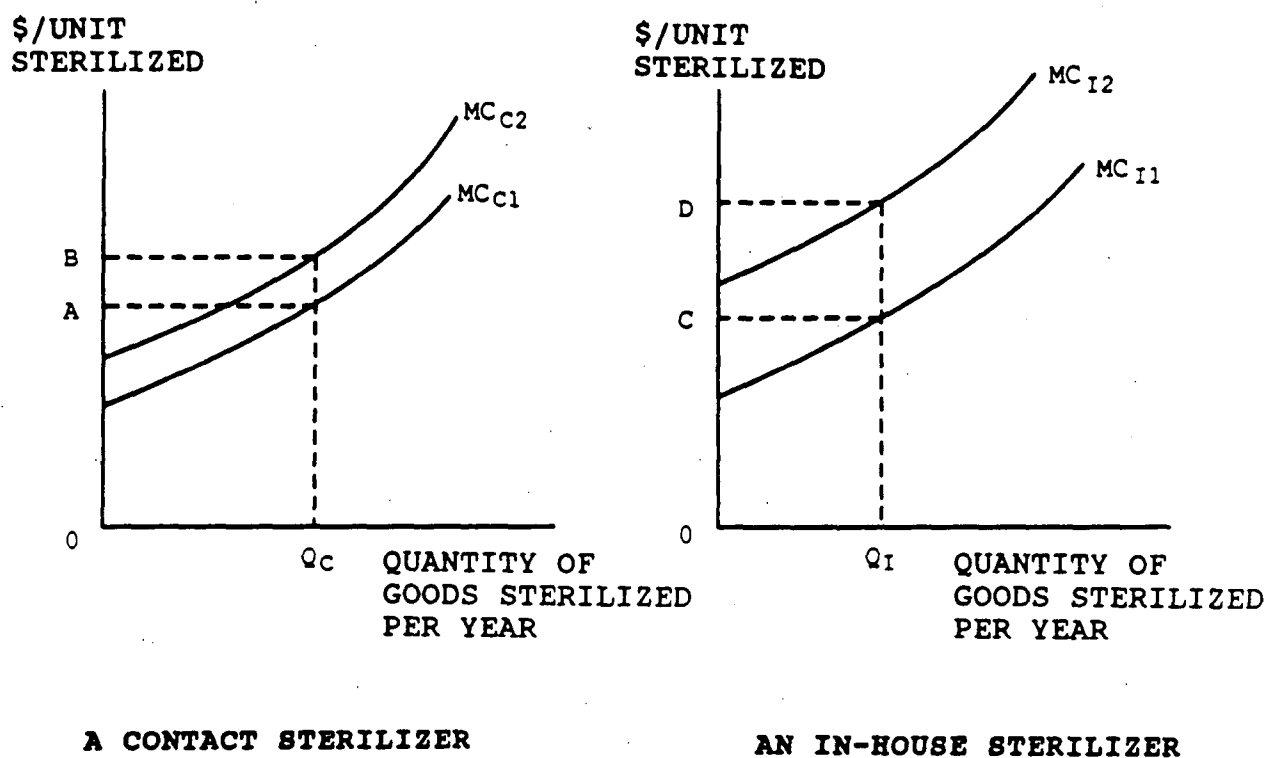


Figure 8-5. Marginal cost curves for a contract sterilizer and an in-house sterilizer, with and without the air emission standard in effect.

regulation in effect is OB. The distance BA measures the TAC/unit for that quantity sterilized. Similarly, if the in-house sterilizer sterilizes Q_I quantity of goods (again, an arbitrarily selected quantity), OC measures the marginal cost of sterilization without the regulation in effect, OD measures the marginal cost of sterilization at output level Q_I with the regulation in place, and DC measures the TAC/unit for that quantity sterilized.

The compliance cost per Mg of EO used should be lower for the contract sterilizers, on average, than for in-house sterilizers. Because of economies of scale in controlling the emissions, larger emitters, such as the contract sterilizers, will incur lower TAC per unit of product sterilized. This expectation is embodied in the relatively larger upward shift in the supply curve for the in-house sterilizer (DC is greater than AB). The economies of scale in compliance are reflected in our estimated costs of compliance. As shown in Tables 8-17 and 8-18, contract sterilizers have the lowest median TAC per Mg of EO used and the lowest median TAC per dollar of annual sterilization cost.

If nothing else changes, the air emission standard results in a higher equilibrium price and a smaller total quantity of contract sterilization performed. However, the demand for contract sterilization is expected to change. Because of their higher per-unit TAC, some of the in-house sterilizers will find that their cost of sterilizing in-house, with the compliance costs imposed, now exceeds the cost of using a contract sterilizer. This condition will increase the market demand for contract sterilization. At baseline, 16 contract sterilizers use approximately 335 Mg (330 tons) of EO per year, and approximately 170 in-house sterilizers use about 1,482 Mg (1,459 tons) of EO per year. If the quantity of EO used is closely related to quantity of goods sterilized, then in-house sterilization accounts for approximately 81 percent of the total quantity of goods sterilized annually. Depending on the cost functions and compliance costs of the individual in-house sterilizers, many of

them may choose to substitute contract for in-house sterilization, resulting in a substantial increase in the market demand for contract sterilization.

Figure 8-6 shows a new equilibrium in the contract sterilization market, with the market supply curve, S_{CM2} , shifted upward by the per-unit TAC of the regulation. The market demand curve, D_{CM2} , is shifted outward as a result of former in-house sterilizers who have decided to substitute contract sterilization for in-house sterilization. In this figure, both the price and quantity of contract sterilization have increased.

This absolute increase in contract sterilization may or may not occur, depending on the actual positions and shapes of the supply and demand curves. Contract sterilization's share of total sterilization will definitely increase, however, because their lower average TAC per unit sterilized will cause some in-house sterilizers to decide to switch to contract sterilization. In this example, contract sterilizers' revenues increase by more than their compliance costs as a result of the regulation. Revenues without the regulation in place are shown by the rectangle OP_1AQ_{C1} , and revenues with the regulation in effect are shown by OP_2CQ_{C2} . The change in revenues is shown by the difference in these two rectangles, shaded in on the graph. The TAC/unit is the vertical distance between the two market supply curves, CB , so the compliance costs as a result of the regulation are shown in the rectangle, DP_2CB . The change in revenues in this case exceeds the compliance costs for the contract sterilization sector.

In summary, adopting the emissions controls on EO sterilization will increase the unit cost of sterilization for both in-house sterilizers and contract sterilizers. Because of economies of scale in controlling emissions, the TAC per unit sterilized will be higher for the in-house sterilizers than for the contract sterilizers. In the new market equilibrium, some in-house sterilizers will probably decide to substitute contract sterilization for their in-house sterilization. The share of contract sterilization in the sterilization market will increase

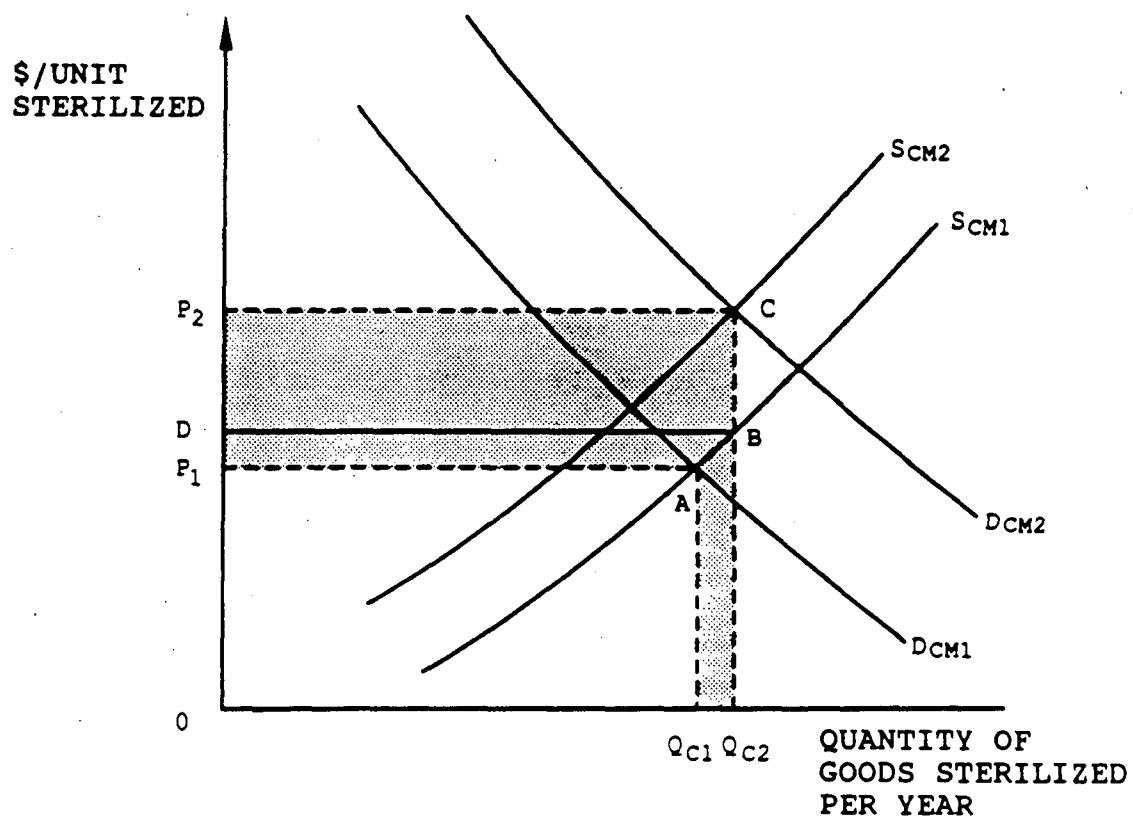


Figure 8-6. The market for contract sterilization with the air emission standard in effect.

as a result of the regulation, and the absolute quantity sterilized may actually increase. In fact, the market price may increase by more than the TAC per unit sterilized for contract sterilizers so that their revenues will increase by more than their costs as a result of the regulation. For these reasons, a regulatory flexibility analysis for contract sterilizers, a more detailed examination of small entity impacts, is not required.

8.7.5 Small Business Impacts in Other Industry Groups

Many of the other industry groups in our analysis include SIC codes for which the actual size definitions in the Federal Register, 13 CFR Part 121, specify numbers of employees, rather than sales. Unfortunately, no employee data for any of the firms are in the data base. Therefore, the sales criterion used for the contract sterilizers was applied. The results are shown in Table 8-20.

Of the approximately 170 facilities in the other industry groups, only 22 are defined as small, based on their estimated sales revenues. Using facility sales as a proxy for total production costs, the number of these facilities that would experience an increase in total production costs of more than 5 percent was estimated. Given this criteria for a significant impact, 1 of the 22 experiences significant impacts under Option 1, 6 of the 22 under Option 2, and 8 of the 22 under Option 3. Another factor to consider when examining the impacts of these small facilities is whether a facility is a major or an area source. If a facility is an area source, it is possible that the facility will be required to adopt less stringent controls than major sources or may even be exempt from the regulation. For this regulation, an area source is a facility that emits less than 10 tons of EO per year. Given this definition, 20 of the 22 small businesses are classified as an area source. As a result of the information presented above and because only a small absolute number of small entities in each industry experience significant impacts as a result of the regulation, it is concluded that a regulatory flexibility analysis is not required.

TABLE 8-20. SMALL BUSINESSES IN THE INDUSTRY GROUPS
PERFORMING IN-HOUSE STERILIZATION

Industry group	No. of -small entities	No. of significant impacts		
		Option 1	Option 2	Option 3
Laboratories	2	0	1	1
Spice manufacturers	3	0	1	1
Pharmaceuticals manu- facturers	2	0	1	1
Other health-related	5	0	0	0
Med. device suppliers	6	1	2	3
Museums and libraries	4	0	1	2

8.7.6 Summary

The majority of contract sterilizers are small businesses, and most of the small businesses in the contract sector will experience compliance costs exceeding 5 percent of baseline sterilization costs. Because contract sterilizers, on average, sterilize larger quantities than in-house sterilizers, they will, on average, experience economies of scale in controlling their emissions. This condition will result in lower total annual compliance costs per unit sterilized for contract sterilizers than for in-house sterilizers, which in turn will result in contract sterilizers having a larger share of the sterilization market with the regulation in effect than they have at baseline. Depending on the extent to which supply and demand for contract sterilization change in response to the regulation, and the characteristics of the supply and demand relationships, contract sterilizers may find that their revenues increase by more than their costs as a result of the regulation. Finally, depending on the positions and shapes of the supply and demand curves, the absolute quantity of contract sterilization performed may actually increase as a result of the regulation. In the other industry groups, only a small absolute number of small firms is significantly affected by the regulation. For these reasons, it is concluded that a regulatory flexibility analysis is not required.

8.8 CONCLUSIONS

In this section conclusions are summarized regarding the economic effects of the candidate NESHAP controls, under each control option, on existing and new facilities.

8.8.1 Effects on Existing Facilities

This study suggests that the candidate NESHAP controls will increase the cost of performing EO sterilization at affected facilities. The incremental costs involved in moving from one control option to the next appear to be substantial, on average. As described at the beginning of this section, the increased cost of sterilization (resulting in shifting the supply curve for sterilized products upward) will probably result in reductions in

the quantities produced of products sterilized using EO and an increase in their prices. Because the data required to estimate the elasticities of supply and demand for the products sterilized using EO are not available, it is not possible to make quantitative estimates of these quantity and price changes.

Faced with the increased costs of sterilization with EO, facilities may choose one of the following four alternatives:

1. Pay the increased costs, implement the controls, and continue to sterilize using EO;
2. Switch from EO sterilization to another onsite sterilization process;
3. Discontinue onsite sterilization and switch to contract sterilization; or
4. Discontinue producing the sterilized product.

Without quantitative estimates of the changes in price and quantity for sterilized products, and without adequate data about the relative costs of the alternatives facing the facility, it is not possible to determine which alternative facilities will choose. However, some facilities will probably decide to discontinue EO sterilization as a result of the candidate NESHAP controls.

Based on the median values reported in Section 8.6.4, the candidate NESHAP is likely to significantly affect three industry groups: museums and libraries, spice manufacturers, and contract sterilizers. The candidate NESHAP will have a substantial effect on all facilities in the museums and libraries group. These facilities have very small chambers and use a very small quantity of EO. Consequently, the TAC/CV and TAC/EO values for museums and libraries are relatively high under all three control options. The TAC/C values indicate that the candidate NESHAP controls will increase sterilization costs by more than 50 percent for many facilities under Option 1 and will more than double sterilization costs for many museums and libraries under Options 2 and 3. Furthermore, the TAC/S values indicate that the costs of the candidate NESHAP controls represent a significant percentage of the operating budget for many of the

museums and libraries. To the extent that museums and libraries do not have ready access to capital markets, they may also have difficulty getting the capital needed to acquire the relevant control devices.

Museums and libraries do, however, have possible substitutes for EO. As discussed in Section 8.1, sulfuryl fluoride, marketed under the trade name Vikane™, may be an acceptable substitute for EO in sterilizing nonmetallic objects. Converting to Vikane as a sterilant involves some costs, including those of chamber modification and training the operators to be certified to apply Vikane™, a registered pesticide. Other possible substitutes include deep freezing, CO₂ fumigation, and vacuum treatment. Converting from EO to any of these would entail some conversion costs. Conversion costs must be compared with the costs of implementing the candidate NESHAP controls and the costs of switching from onsite sterilization to using a contract sterilizer. Depending on the relative costs, some facilities may choose to continue onsite sterilization, others may switch to Vikane, and still others may use a contract sterilizer. Alternatively, some museums and libraries may decide to use the services of a contract sterilizer or discontinue fumigation altogether, because of a lack of the capital needed either to implement the candidate NESHAP controls or to switch to Vikane™. Also, some facilities may conclude that the value they receive from fumigation does not justify the additional cost of implementing controls, employing a contract sterilizer, or converting to Vikane™.

The TAC/CV and TAC/EO are also fairly large for the facilities in the laboratories group, because of the below-average size of their sterilization chambers and relatively small quantity of EO they use. Nevertheless, the TAC/S and TAC/C values for this group are low, suggesting that sterilization costs are a very small part of total production costs at these facilities. Without knowing the precise figure, an animal-breeding laboratory indicated that sterilization costs are "surely less than 1 percent of total production cost."³³

The TAC/C median values for the medical device suppliers, other health-related suppliers, and pharmaceutical manufacturers range from 16.0 percent to 20.4 percent under Option 1, from 16.6 percent to 31.6 percent under Option 2, and from 24.4 percent to 40.1 percent under Option 3. Thus, the candidate NESHAP controls will substantially increase sterilization costs in the industry groups. However, sterilization costs are generally very small relative to the total cost of producing sterilized products in these industries. For example, a pharmaceutical manufacturer estimated that sterilization costs represent only about 3 percent of total production costs.⁸ Consequently, the candidate NESHAP controls probably will not significantly increase production costs for most medical device suppliers, other health-related manufacturers, or pharmaceutical manufacturers. The very low TAC/S values for these industry groups support this expectation. Although median values do not indicate significant impacts, individual facilities in each of these industries might incur significant adverse impacts.

Spice manufacturers incur relatively low unit compliance costs, as shown by TAC/CV and TAC/EO. At the same time, they incur some significant increases in sterilization costs, as measured by TAC/C. Their median TAC/C is the second highest, almost 45 percent under Option 1, 52 percent under Option 2, and 68 percent under Option 3. Also, the most severely affected facilities in this sector incur compliance costs greater than their baseline costs under Option 1, nearly 1.5 times their baseline costs under Option 2, and nearly twice their baseline costs under Option 3. Fortunately, sterilization represents a small proportion of total production costs in this industry (TAC/S is less than one percent, even under Option 3). Also, a good substitute exists for EO fumigation in the spice manufacturing industry: radiation. As described in Section 8.1, an industry source stated that radiation has several advantages over EO fumigation.¹⁶ These advantages include killing all bacteria, rather than only a large percentage of bacteria. Second, radiation can be done under ambient conditions. Third,

radiation leaves no residue and requires no aeration. It does, however, entail the costs of purchasing the equipment needed to irradiate the product and training employees to use the new equipment. No information is available about the relative costs of radiation and EO as sterilization techniques. The candidate NESHAP will probably significantly affect many contract sterilizers. For the other industry groups in this study, sterilization is one of many steps in the production process. In contrast, sterilization is nearly the entire "product" for contract sterilizers. (As discussed in Section 8.1, many contract sterilizers may also perform some packaging, testing, and distribution services that are linked to their sterilization operations.) Thus, the candidate NESHAP will probably cause a more pronounced increase in contract sterilizers' production costs, which is reflected in the relatively high median TAC/S (2 percent under Option 1, 3.9 percent under Option 2, and 4.6 percent under Option 3) for contract sterilizers. [As noted earlier, one of the shortcomings of total sales is that it includes sales of sterilized and nonsterilized products; because virtually all sales from contract sterilizers involve sterilized products, this shortcoming would tend to result in higher TAC/S for these facilities than for facilities in the other industry groups.]

In addition to significantly increasing their sterilization costs, the candidate NESHAP may result in increased demand for contract sterilization services. Because contract sterilizers on average have larger chambers than the other industry groups and run more EO through them, the per-unit cost of the candidate NESHAP is less for contract sterilizers than for the other groups. This conclusion is supported by the data in Tables 8-14 through 8-19, which indicate that contract sterilizers have the lowest median TAC/CV, TAC/EO, and TAC/C of the seven industry groups under all three control options. As explained in Section 8.7, the contract sterilizers' lower per-unit control costs may actually cause them to gain additional business if

firms switch from in-house sterilization to contract sterilization.

Aside from the effects of the candidate NESHAP controls on the museums and libraries group, the contract sterilizers group, and perhaps the spice manufacturers group, significant effects may occur at some individual facilities in the other five industry groups. In general, these are the facilities with the highest TAC/S values in the groups. These facilities may choose to incur the relatively high control costs, to switch to another sterilization process, to switch from in-house to contract sterilization, or to discontinue their production of sterilized products. Without further information on these facilities, there is no way to predict which response will be chosen in each case.

8.8.2 Effects on New Facilities

Up to this point the analysis has focused on the economic effects of the candidate NESHAP controls on existing facilities. Without data on possible control costs for new (not-yet-constructed) facilities in each industry group, making any quantitative estimates of the potential effects of the candidate NESHAP, under each control option, on these facilities was not possible. Nevertheless, some general conclusions may be reached on this matter based on the information presented earlier in this chapter.

The supply curve for products sterilized using EO will shift upward as a result of the candidate NESHAP controls. If the demand curves for these products are at all elastic, the quantity of the products sold will decrease. This decrease will delay investment in new facilities that would use EO.

The effect on investment by contract sterilizers is more difficult to predict. Because some facilities in the other six industry groups may decide to switch from in-house sterilization to contract sterilization, the demand curve for contract sterilization may shift out as a result of the candidate NESHAP controls. The market share of contract sterilization will increase, and the absolute quantity of contract sterilization may increase. Depending on the change in the profitability of

contract sterilizers resulting from the candidate NESHAP controls, some additional investment by contract sterilizers might occur.

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APPENDIX A.

EVOLUTION OF THE BACKGROUND INFORMATION DOCUMENT

TABLE A-1. EVOLUTION OF THE BACKGROUND INFORMATION DOCUMENT

Date	Event
October 2, 1985	The EPA announces intent to list ethylene oxide (EO) as a hazardous air pollutant under Section 112 of the Clean Air Act (Act) (50 FR 40286).
October 1985	Collection of background information begun by Midwest Research Institute.
January 8, 1986	Site visit to Sterilization Services of Tennessee to observe sterilization and gas reclamation facilities.
January 13, 1986	Site visit to North Carolina Archives and Records to observe EO fumigation chamber and obtain data on EO use.
January 16, 1986	Site visit to McCormick and Company, Inc., to observe EO fumigation chambers and Deoxx™ control system.
April 2, 1986	Meeting with Johnson and Johnson (J&J) International and Damas Corporation to discuss the EO scrubber manufactured by Damas and used by J&J.
April 1986	Data received from a Health Industry Manufacturers' Association (HIMA) survey performed in November of 1985 are compiled in the Commercial Sterilization data base.
July 1986	Questionnaires sent to miscellaneous sterilization and fumigation facilities. Responses were received from 113 of these facilities.
August 1987	Mail out Chapters 3-5 of the background information document (BID) for review.
August 27, 1987	Work Group briefing.
September 30, 1987	Meeting with HIMA short-term exposure limit task force to discuss industry's response to the EO and chlorofluorocarbon (CFC) BID mailouts.
November 13, 1987	Second Work Group briefing.
March 11, 1988	NAPCTAC mailout of BID chapters and Appendices.
March 23, 1988	Docket No. A-88-03 (Commercial Sterilization) is submitted.

TABLE A-1. (continued)

Date	Event
May 19, 1988	NAPCTAC meeting.
July 1988	Questionnaires sent out to miscellaneous sterilization and fumigation facilities. Responses were received from 44 facilities.
December 9, 1988	Site visit to Iolab, Inc., to obtain information about the DM3 Catcon catalytic oxidation system used to control emissions from the aeration room.
December 9, 1988	Site visit to Medtronic, Inc., to obtain information about the acid-impregnated carbon adsorption system used to control emissions from the aeration room.
February 21, 1989	Teleconference with HIMA to discuss progress on the standard.
November 3, 1989	Meeting with HIMA to discuss progress on the standard.
December 4-6, 1989	Vendor-sponsored test of Donaldson Eto Abator™ catalytic oxidizer.
December 12, 1989	Review of a summary of the prevalence of chamber exhaust use among HIMA members.
June 14, 1990	Site visit to Isomedix Operations, Inc., to obtain information about their sterilization processes.
August 7, 1990	Work Group meeting on regulatory alternatives.
January 30, 1991	NAPCTAC meeting.

APPENDIX B.
INDEX TO ENVIRONMENTAL CONSIDERATIONS

APPENDIX B.

INDEX TO ENVIRONMENTAL CONSIDERATIONS

This appendix consists of a reference system which is cross-indexed with the October 21, 1974, Federal Register (39 FR 37419) containing Agency guidelines for the preparation of Environmental Impact Statements. This index can be used to identify sections of the document which contain data and information germane to any portion of the Federal Register guidelines.

APPENDIX B.
INDEX TO ENVIRONMENTAL IMPACT CONSIDERATIONS

Agency guidelines for preparing regulatory action environmental impact statements (39 FR 37419)	Location within the background information document (BID).
1. Background and description	
Summary of the regulatory alternatives	The regulatory alternatives are summarized in Chapter 1.
Statutory authority	Statutory authority is given in Chapter 1 and Chapter 2.
Industry affected	A description of the industry to be affected is given in Chapter 8.
Sources affected	Descriptions of the various sources to be affected are given in Chapter 3.
Availability of control technology	Information on the availability of control technology is given in Chapter 4.
2. Regulatory alternatives	
Regulatory alternative A	
Environmental impacts	Environmental effects of regulatory alternative A are considered in Chapter 6.
Costs	Costs associated with regulatory alternative A are considered in Chapter 7.
Regulatory alternative B	
Environmental impacts	Environmental effects of regulatory alternative B emission control systems are considered in Chapter 6.
Costs	Costs associated with regulatory alternative B emission control systems are considered in Chapter 7.

Agency guidelines for preparing regulatory action environmental impact statements (39 FR 37419)	Location within the background information document (BID).
<p>Regulatory alternative C</p> <p>Environmental impacts</p> <p>Costs</p>	<p>Environmental effects of regulatory alternative C emission control systems are considered in Chapter 6.</p> <p>Costs associated with regulatory alternative C emission control systems are considered in Chapter 7.</p>
<p>Regulatory alternative D</p> <p>Environmental impacts</p> <p>Costs</p>	<p>Environmental effects of regulatory alternative D emission control systems are considered in Chapter 6.</p> <p>Costs associated with regulatory alternative D emission control systems are considered in Chapter 7.</p>
<p>Regulatory alternative E</p> <p>Environmental impacts</p> <p>Costs</p>	<p>Environmental effects of regulatory alternative E emission control systems are considered in Chapter 6.</p> <p>Costs associated with regulatory alternative E emission control systems are considered in Chapter 7.</p>

APPENDIX C.
EMISSION SOURCE TEST DATA

APPENDIX C.

EMISSION SOURCE TEST DATA

This appendix contains summaries of performance tests EPA and industry conducted on four acid-water scrubbers and one catalytic oxidizer designed to control ethylene oxide (EO) emissions from sterilizer exhaust and aeration room gas streams, respectively. Performance tests to determine control device efficiency were conducted on two types of acid-water scrubber systems, Damas™ and DEOXX™. Detailed descriptions of these types of scrubbers are presented in Chapter 4. The sterilizers tested use pure EO and a 12/88 mixture of EO and chlorofluorocarbons (CFC's) as sterilant gases. The results of the five tests are presented in the following sections of this appendix:

C.1--EPA test of a DEOXX™ system at Burrion Medical;

C.2--Independent laboratory test of a DEOXX™ system at McCormick and Company, Inc.;

C.3--Independent laboratory test of a DAMAS™ system at Johnson and Johnson, Inc.;

C.4--Independent laboratory test of a DEOXX™ system at Chesebrough-Pond's DEOXX™ facility; and

C-5--Vendor test of an EtO ABATOR™ system at Seamless, Inc.

A summary of the test results and selected test conditions for the first four tests is provided in Table C-1.

C.1 EPA TEST OF A DEOXX™ SYSTEM AT BURRION MEDICAL

C.1.1 Facility Description¹

An EPA-sponsored test was conducted on a Deoxx™ acid-water scrubber in September 1987. The test took place at Burrion Medical, a medical supply sterilization facility located in Allentown, Pennsylvania. The facility has three 28 cubic meters

TABLE C-1. SUMMARY OF TEST RESULTS

Plant	Scrubber type	Chamber size, m ³ (ft ³)	Sterilant	No. of runs	Flow rate, m ³ /s (ft ³ /min)	Range of EO inlet concentrations, ppmv	Range of EO outlet concentrations, ppmv	Average percent removal
Burron Medical	DEOXX™	28.3 (1,000)	12/88	10 ^a	b	b	b	99.96 ^c
McCormick & Company	DEOXX™	35.3 (1,248)	Pure EO	3	d	26,800 - 385,000	<5 - 458	99.988
Johnson & Johnson	Damas™	b	12/88	6	0.031 (66)	b	14 - 1,938	99.25
			12/88	3	0.047 (100)	b	12 - 1,853	99.26
Chesebrough-Pond's, Inc.	DEOXX™	35.7 (1,260)	12/88	3	d	1,000 -	<1 - 10,000	>99.93
		35.7 (1,260)	Pure EO	1	d	250,000	<1-10,000	>99.99

^aSeventeen tests were performed; data from 10 of these tests were used in the report.

^bData not provided.

^cBased on throughput efficiency for empty chamber runs.

^dFlow rate varies widely for the various runs and evacuations.

(m³) (1,000 cubic feet [ft³]) sterilizers that use 12/88. The gas is supplied from a common header serving all four units and is controlled by a liquid flow meter.

A sterilization cycle typically uses 140 liters (L) (38 gallons [gal]) of 12/88 gas mixture. On a weight basis, a sterilization charge consumes 167 kilograms (kg) (368 pounds [lb]) of gas, of which approximately 20 kg (44 lb) are EO. The initial charge of EO to the chamber was calculated using the weight of the supply cylinders before and after charging the chamber.

The exhaust from the sterilizers is controlled by a DEOXX™ system. At the time of the test, the scrubber contained a dilute mixture of phosphoric and sulfuric acid. Each chamber is equipped with a total recirculating liquid vacuum pump. These pumps are equipped with gas/liquid separators, which emit the gas to the DEOXX™ system and recirculate the liquid to the pump inlet. Chambers Nos. 1 and 2 are equipped with oil-sealed pumps. Chamber 3 is equipped with a water-sealed pump. All of the tests were conducted using the chambers (Nos. 1 and 2) equipped with oil-sealed pumps.

The sterilization cycle is controlled automatically by a programmable microprocessor system. The control system can control and record the parameters of the sterilization cycle including chamber temperature, chamber pressure, and elapsed time from the start of the cycle.

The sterilization process begins with a humidifying step, which takes place in a separate room. After the humidifying step, each load to be sterilized is transferred to the sterilization chamber. The sterilization cycle is a batch process that takes 4 to 6 hours. A sterilizer load begun during the morning shift exhausts at about 2:00 p.m. In a typical plant operating mode, seven poststerilization evacuations occur over a 3-hour period. After the chamber is repressurized, following the seventh evacuation, the product is removed from the chamber and allowed to off-gas. Although the control system is designed to handle the exhaust from two sterilizers venting simultaneously,

the tested sterilization cycles were scheduled so that only one sterilizer vented at a time.

Three different sterilization programs were used for testing: one for the empty chamber tests, one for the full chamber tests, and one for the last full chamber test (Test 13). The testing of both full (loaded) and empty chambers was carried out to examine the effects of product retention of EO on the EO emissions. A total of 17 tests were performed, 5 with product in the chamber (full chamber tests) and 12 without product (empty chamber tests). Seven of these tests were considered invalid according to the testing lab, therefore, data from 10 of these tests (4 with and 6 without product) were summarized in the final report. Table C-2 summarizes operating data from the 10 valid tests.

Before the start of each test (except Test 13), the chamber was evacuated to 2 pounds per square inch absolute (psia) and then pressurized to 3.1 psia with steam. The humidifying step was maintained at 3.1 psia for 1 hour for the loaded chamber tests, but the humidifying step was shortened to 5 minutes for the empty chamber tests. After the humidifying, the chamber was charged to 23.9 psia with 12/88 gas. The exposure at 23.9 psia was maintained for 4 hours for the loaded chamber tests but was shortened to 5 minutes for the empty chamber tests. During the last full chamber test (Test 13), the chamber was evacuated to 7 psia and pressurized to 32.9 psia.

Each test program contained seven poststerilization evacuations; an initial chamber evacuation, six air in-bleeds with subsequent evacuations, and a final air in-bleed. Except in Test 13, the chamber was evacuated to 2 psia and pressurized with air to 13.9 psia during each evacuation and air in-bleed cycle. The initial chamber evacuation and pump down lasted 26 to 27 minutes. Each subsequent evacuation lasted 12 to 14 minutes, and each air in-bleed required 12 to 14 minutes. During Test 13, the chamber was evacuated to 7.0 psia, which reduced each evacuation and air in-bleed time by 7 minutes.

TABLE C-2. SUMMARY OF FIELD TESTS AT BURRON MEDICAL¹

Test No.	Product present	Chamber No.	Weight of 12/88 used, lb	Test date	Test start time	Test end time
6 ^a	Yes	2	368	87/10/06	21:39	00:38
7 ^b	No	1	365	87/10/07	10:19	14:04
8 ^a	Yes	2	388	87/10/07	15:10	18:11
9 ^b	No	1	346	87/10/08	09:25	12:42
10 ^b	No	1	353	87/10/08	14:41	17:48
11 ^a	Yes	2	392	87/10/08	18:00	21:01
12 ^b	No	1	346	87/10/09	12:44	15:53
13 ^c	Yes	2	442	87/10/09	16:16	18:03
14 ^b	No	1	350	87/10/10	08:54	12:01
15 ^b	No	1	343	87/10/10	13:35	16:43

^aThe chamber was evacuated to 2 psia before being pressurized with steam to 3.1 psia. Humidification step lasted 1 hour, and then the chamber was charged to 23.9 psia with 12/88. Exposure lasted 4 hours. Poststerilization chamber pressure cycled between 2 psia and 13.9 psia.

^bThe chamber was evacuated to 2 psia before being pressurized with steam to 3.1 psia. Humidification step lasted 5 minutes, and then the chamber was charged to 23.9 psia with 12/88. Exposure lasted 5 minutes. Poststerilization chamber pressure cycled between 2 psia and 13.9 psia.

^cThe chamber was evacuated to 7 psia before being pressurized with steam to 8 psia. Humidification step lasted 1 hour, and then the chamber was charged to 32.9 psia with 12/88. Exposure lasted 5 hours. Poststerilization chamber pressure cycled between 7 psia and 13.5 psia.

C.1.2 Sampling Procedures¹

The sampling and analysis procedure used in these field tests involved semicontinuous direct sampling of scrubber inlet and outlet gas streams with on-line gas chromatographic analysis to determine EO concentrations. Volumetric flow rates both entering and exiting the scrubber were determined with orifice plates. However, some difficulty was encountered when measuring the inlet volumetric flow rate due to the high EO concentration and low flow rate of the gas stream.

C.1.3 Test Results¹

Table C-3 presents uncontrolled and controlled emissions (i.e., the amount of EO entering and exiting the control unit) for the six empty chamber tests. Emission measurements were considered for the six empty chamber tests because the total amount of EO entering the scrubber were more consistent for these runs. These emissions measurements were used to evaluate the EO control efficiency of the DEOXX™ system.

Efficiencies were calculated for the six test runs. Throughput efficiency was calculated using the gas stream EO concentrations and volumetric flow rates into and out of the DEOXX™ unit. This method calculates the efficiency of the control device, i.e., the difference in mass of EO into and out of the control device. However, the method used to determine this efficiency suffered due to the inability of the orifice plates to accurately measure the flow rate into the scrubber. The second method of determining control efficiency, recovery efficiency, was calculated using the weight of the original EO charge and the measured EO emissions at the outlet of the control unit.

Both of the analytical methods used to determine control efficiency were hindered by the difficulty in determining the GC peak for EO scrubber outlet concentration measurements. This problem arose from a shift in the EO retention time (in the column of the GC) as EO concentrations exiting the scrubber decreased. The difficulty in identifying the EO peak was further

TABLE C-3. SUMMARY OF EMISSION MEASUREMENTS AND CONTROL EFFICIENCIES FOR
EMPTY CHAMBER TESTS AT BURRON MEDICAL¹

Test No.	Initial EO charged to chamber, kg (lb)	EO left in chamber, kg (lb)	EO entering control unit, kg (lb)	EO exiting control unit, kg (lb)	Throughput efficiency, percent ^a	Recovery efficiency, percent ^b
7 ^c	19.9 (43.8)	0.19 (0.42)	10.98 (24.19)	0.020 (0.043)	99.82	99.90
9	18.8 (41.5)	0.68 (1.50)	27.51 (60.59) ^d	0.005 (0.011)	99.98	99.97
10	19.2 (42.4)	0.10 (0.22)	28.20 (62.12) ^d	0.013 (0.029)	99.95	99.93
12	18.8 (41.5)	0.07 (0.16)	19.98 (44.00)	0.005 (0.011)	99.98	99.97
14	19.1 (42.0)	0.07 (0.16)	22.16 (48.80)	0.010 (0.021)	99.96	99.95
15	18.7 (41.2)	0.03 (0.07)	23.98 (52.82)	0.006 (0.014)	99.97	99.97

^aCalculated using the measured EO entering and exiting the control device.

^bCalculated using the weight of the original EO charge and the measured EO emitted at the outlet of the control device.

^cDuring Test 7, there was a leak in the inlet sampling pump during the first 10 minutes of the evacuation, and the flame ionization detector (FID) flame was extinguished during portions of the third and fourth evacuations. Loss of these samples may explain the lower mass of EO entering the control unit during this test.

^dThe EO standard calibration curve for inlet samples on October 8, 1987 was lower than on the other test days. This unusually low value would have raised the measured EO concentrations and caused the EO mass flow into the control unit to be overestimated.

C-7



223

complicated by the large range of EO concentrations exiting the scrubber.

Statistical tests were performed to evaluate the effect of product in the chamber on determining the efficiency of the control unit. These tests showed that the presence of product in the chamber had no significant effect on the efficiency determinations.

The absolute difference between measured emissions and expected emissions (based on the initial EO charge to the chamber) was greater than 40 percent for three tests and less than 10 percent for only one test. In five of the six empty chamber tests, the measured emission levels were higher than the expected levels. From these observations, actual uncontrolled EO emissions may therefore be expected to be from 50 to 150 percent of the actual emissions.

C.2 INDEPENDENT LABORATORY TEST OF A DEOXX™ SYSTEM AT MCCORMICK AND COMPANY, INC.

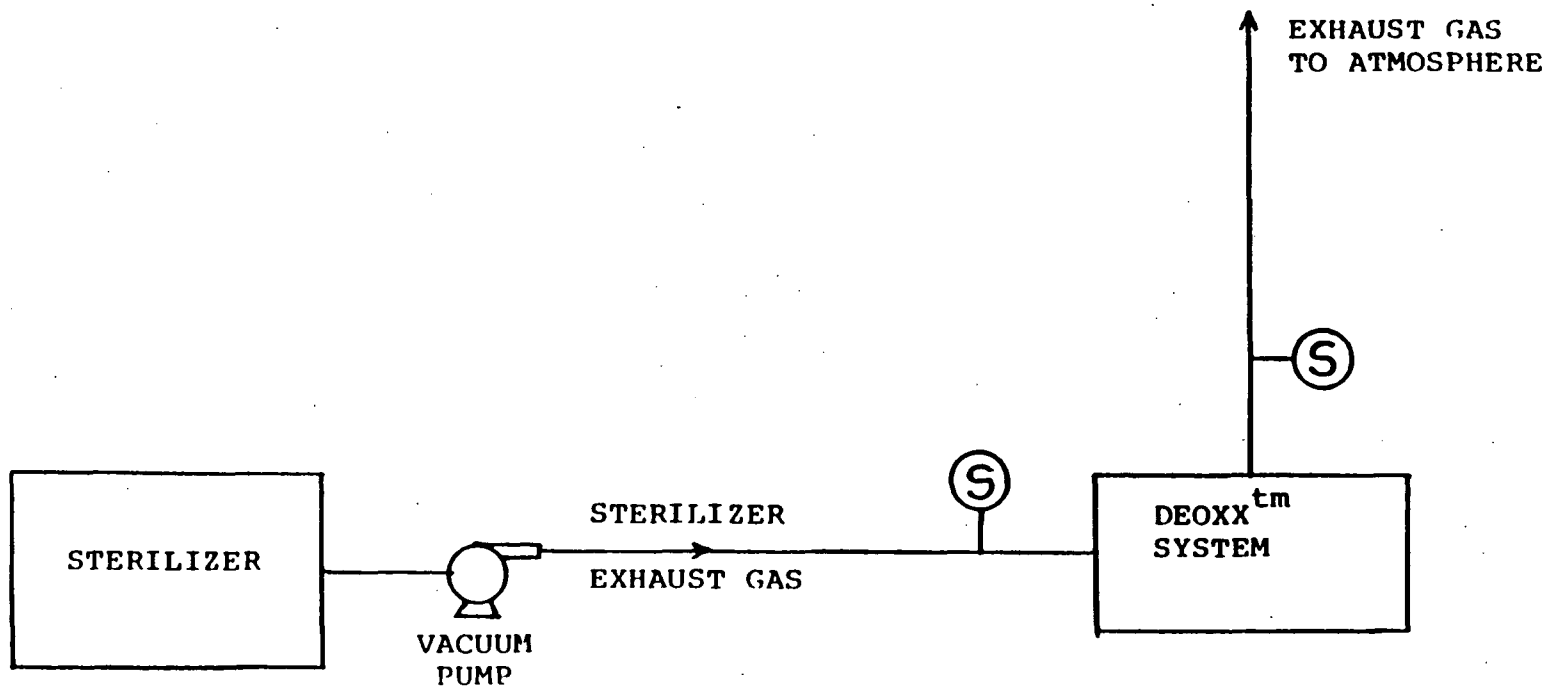
C.2.1 Facility Description²

A DEOXX™ detoxification system was installed at the Hunt Valley Spice Mill of McCormick and Company to control EO emissions from sterilizers. The DEOXX™ system was tested by an independent laboratory the week of October 14, 1985, to evaluate performance.

The sterilizers at the Hunt Valley Spice Mill are used to process a variety of spices. Pure EO is used as the sterilant. Each sterilizer is equipped with a total-recirculation liquid ring vacuum pump system to evacuate the chamber and achieve the desired levels of vacuum. At the completion of the sterilization cycle, sterilizer gas is exhausted to the atmosphere through the DEOXX™ system.

A test program consisting of four tests was conducted using Sterilizer B, which had a volume of 35.3 m³ (1,248 ft³). The first test was used to check the equipment and instrumentation operation. The remaining three tests (Test Nos. 2, 3, and 4) were used to evaluate the DEOXX™ system performance. Figure C-1 provides locations of the sampling points.

C-9



- Ⓢ : SAMPLING POINT TO MEASURE
- ETO CONCENTRATION
 - VOLUMETRIC GAS FLOWRATE
 - GAS TEMPERATURE
 - GAS STATIC PRESSURE

Figure C-1. Sampling point locations.²

The sterilization cycle operating conditions for the three performance tests are summarized below:

Initial evacuation conditions:

Pressure, psia (in. Hg)	14.2 (28.9)
Time, min	25

Total EO charged to chamber, kg (lb):

Test 1	13.2 (29.0)
Test 2	13.2 (29.0)
Test 3	12.7 (28.0)

Exposure conditions:

Pressure, psia (in. Hg)	10.4 (21.2)
Temperature, °C (°F)	43.3 (110)

Following the sterilization cycle, the chamber was evacuated to 7.0 psia (14.3 in. Hg) over a period of 12 minutes. Two additional evacuations lasted 10 minutes each, and the air washes required less than 1 minute each.

C.2.2 Sampling Procedures²

The sterilization chamber was kept empty during the test cycles. This eliminated possible variations in EO emissions during the exhaust phase due to product off-gassing without adversely affecting the performance evaluation of the DEOXX™ system.

For each performance test cycle, the amount of EO charged to the sterilizer was determined by measuring the weight of the EO supply cylinder before and after charging EO to the sterilizer chamber.

The weights of EO entering and leaving the DEOXX™ system were determined for each chamber evacuation by continuously monitoring the total volumetric gas flow rate and EO concentration at the inlet and the outlet of the DEOXX™ system. The volumetric gas flow rate was measured by using an orifice meter at each location. The gas pressure drop across the orifice plate was monitored throughout the exhaust cycle for accurate measurement of gas flow rate. The EO concentrations were

measured with two gas chromatographs, one each at the inlet and the outlet of the DEOXX™ system.

C.2.3 Test Results

The weights of EO entering and leaving the DEOXX™ system for each evacuation, as well as the removal efficiencies associated with each test run, are presented in Table C-4.

C.3 INDEPENDENT LABORATORY TEST OF A DAMAS™ SYSTEM AT JOHNSON & JOHNSON, INC.³

C.3.1 Facility Description

A Damas™ scrubber is used to control EO emissions from the sterilization operations at Johnson & Johnson's Ethicon, Inc., facility in Somerville, New Jersey. During the week of August 27, 1984, a Damas™ scrubber at this facility was tested by an independent laboratory. The sterilizer uses a 12/88 mixture of EO/CFC as the sterilant. All concentrations reported are based on gas chromatograph (GC) analyses.

C.3.2 Sampling Procedures

Nine analyses were performed on the scrubber outlet: six with a scrubber flow rate of 0.031 cubic meters/second (m^3/sec) (66 cubic feet per minute [ft^3/min]) (Set 1) and three with a flow rate of 0.047 m^3/sec (100 ft^3/min) (Set 2). These two sets of analyses were performed on August 29 and August 30, 1984, respectively. Samples were collected by drawing a small amount of the scrubber emission stream through a Teflon™-lined pump to a mobile laboratory using a Teflon™ sample line. A collection sump with a sampling port allowed samples to be drawn with a syringe for injection into a GC with a flame ionization detector. These syringe samples were taken once every 2 minutes during each analysis. The scrubber outlet emission stream was also continuously monitored using an infrared analyzer.

The scrubber inlet gas stream was tested on August 30, 1984, using a scrubber flow rate of 0.047 m^3/sec (100 ft^3/min). Three grab samples were collected (during one evacuation) in Tedlar™ bags and analyzed in the same manner as the scrubber outlet samples. The EO concentration at the scrubber inlet was based on an average concentration of these three samples.

TABLE C-4. SUMMARY OF EMISSION MEASUREMENTS AND CONTROL EFFICIENCIES FOR
TESTS AT THE MCCORMICK AND COMPANY, INC., SPICE MILL²

Test no.	Initial EO charged to chamber, kg (lb)	EO left in chamber, kg (lb)	EO entering control unit, kg (lb)	EO exiting control unit, kg (lb)	Throughput efficiency, percent ^a	Recovery efficiency, percent ^b
2	13.2 (29.0)	0.32 (0.71)	12.19 (26.85)	0.00130 (0.00287)	99.989	99.990
3	13.2 (29.0)	0.30 (0.67)	12.02 (26.47)	0.00140 (0.00309)	99.988	99.989
4	12.7 (28.0)	0.32 (0.70)	11.99 (26.41)	0.00169 (0.00372)	99.986	99.987

^aCalculated using the emission entering and exiting the control device.

^bCalculated using the weight of the original EO charge and the measured EO emissions at the outlet of the control device.

C.3.3 Test Results

The peak outlet concentration for each analysis was used to calculate the removal efficiency of the scrubber. The average scrubber efficiency was 99.25 percent for Set 1 and 99.28 percent for Set 2. The average removal efficiency for all nine runs was 99.26 percent.³ (The average removal efficiency determined by infrared analysis of the scrubber outlet EO concentration was 99.16 percent.)

The use of concentration differences, rather than a percent weight removal, as a basis for calculating the removal efficiency did not significantly affect the efficiency estimate; the efficiency still should be equal to or greater than 99.0 percent. The use of an average inlet concentration, which was based on the highest gas flow rate, and the peak outlet concentration to determine the efficiency would provide a conservative estimate as long as the outlet flow rate is less than or equal to the inlet flow rate. However, if the outlet flow exceeds the inlet flow (e.g., if there is dilution at the stack), then the methodology would overestimate the efficiency. It could not be determined from the data provided whether the outlet and inlet flow rates were different, and there were no indications in the report that flow rates were monitored.³

Some uncertainties exist regarding the efficiencies obtained in this test because of the conditions under which the scrubber was tested. First, the test was performed on a scrubber that was using fresh scrubbing liquor (i.e., no ethylene glycol in the scrubbing liquor). Secondly, it was unclear from the test report whether all the runs each day (i.e., number of evacuations) were for a single sterilization cycle. Finally, there were no indications that gas stream flow rates were monitored during the test.

C.4 INDEPENDENT LABORATORY TEST OF A DEOXX™ SYSTEM AT CHESEBROUGH-POND'S DEOXX™ FACILITY⁴

C.4.1 Facility Description

A DEOXX™ system was installed on sterilizer 4 at Chesebrough-Pond's Sherburne, New York, plant in 1982 to control EO emissions. Four tests were conducted on December 1982 over three different sterilization cycles to evaluate the performance of the system. These tests were performed using pure EO and 12/88 sterilant, and were all conducted on an empty chamber.⁴ This chamber had a volume of 35.7 m³ (1,260 ft³) and was capable of using either pure EO or a mixture of 12/88 EO/CFC as the sterilant gas.

C.4.2 Sampling Procedures

A total of four performance tests was conducted on the DEOXX™ system: three using the 12/88 mixture and one using pure EO gas. The scrubber outlet emission stream was sampled once every minute by routing two sampling streams from the scrubber exhaust to two separate GC's. The volumetric flow rate of the scrubber outlet emission stream was also monitored using an orifice plate. Volumetric flow vs EO concentration profiles were then developed to calculate the mass of EO exiting the scrubber.

The amount of EO entering the scrubber was determined by weighing the sterilant supply cylinders before and after use, and then subtracting the remaining sterilant in the chamber after the cycle. The EO concentration remaining in the chamber was measured with a GC, and the chamber pressure was measured; the ideal gas law was used to determine the weight of EO left in the chamber.

C.4.3 Test Results

A summary of the emission measurements and control efficiencies for these emissions tests is presented in Table C-5. The efficiencies were calculated based on the total weight of EO entering and exiting the scrubber over the entire cycle. The removal efficiencies for the three 12/88 mixtures were 99.0 percent, 98.7 percent, and 99.4 percent, respectively, for

TABLE C-5. SUMMARY OF EMISSION MEASUREMENTS AND CONTROL EFFICIENCIES
FOR EMPTY CHAMBER TESTS AT CHESEBOROUGH PONDS⁴

Test no.	Initial EO charged to chamber, kg (lb)	EO left in chamber, kg(lb)	EO centering control unit, kg (lb)	EO exiting control unit, kg (lb)	Throughput efficiency, percent ^a	Recovery efficiency percent ^b
1	13.7 (30.1)	0.10 (0.22)	13.6 (29.9)	0.14 (0.31)	99.0	98.9 +
2	28.8 (63.4)	0.08 (0.18)	28.7 (63.2)	0.37 (0.81)	98.7	98.7
3	24.0 (53.0)	0.01 (0.02)	24.0 (53.0)	0.0004 (0.001)	99.9 +	99.9 +
4	30.6 (67.4)	0.04 (0.10)	30.5 (67.3)	0.19 (0.42)	99.4	99.4

^aCalculated using the emissions entering and exiting the control device.

^bCalculated using the weight of the original EO charge and the measured EO emissions at the outlet of the control device.

an average of 99.0 percent. For the pure EO mixture, the EO removal efficiency was greater than 99.99 percent.⁴

C.5 VENDOR TEST OF AN ETO ABATOR™ SYSTEM AT SEAMLESS, INC.⁵

C.5.1 Facility Description

A Donaldson EtO Abator™ catalytic oxidizer was installed to control aeration room emissions at Seamless' Ocala, Florida, facility. Testing was performed on the catalytic oxidizer on December 4 through 6, 1989. The control system was installed to demonstrate to the State that Seamless could comply with the State's 1 ppm standard at 50 feet from the fenceline.⁶ This facility sterilizes products in any one of three sterilizer chambers using pure EO or 12/88 (EO/freon) sterilant, depending on which sterilizer is used. After the product is sterilized, it is taken to the aeration room, where it is then allowed to off-gas for at least 24 hours.

The aeration room is maintained at a temperature of 38°C (100°F), and the EO emissions are controlled by two 56 m³/min (2,000 ft³/min) catalytic oxidizers. These units run continuously and provide enough heated, recirculated air to maintain the aeration room at a temperature of 38°C (100°F).

C.5.2 Sampling Procedures

Velocity measurements were performed using Pitot tubes situated at 12 traverse points along the cross-section of the duct both upstream and downstream of the control device. Emission stream temperature measurements were also made at these locations. The averages for each set of measurements were used to determine the emission stream flow rates to and from the control device, respectively.

Six 1-liter grab samples were taken simultaneously both upstream and downstream of the control device via test ports. Two additional 4-liter grab samples (taken in 10-liter Tedlar™ bags) were simultaneously taken both upstream and downstream of the control device. Of the eight sets of samples, five were taken approximately 3 hours prior to introducing sterilized product into the aeration room, two were taken just prior to introducing sterilized product into the aeration room, and one

was taken one-half hour after sterilized product was introduced to the aeration room. These samples were analyzed within a 20-hour period of obtaining the samples using a gas chromatograph with a flame ionization detector (FID). All of the product introduced to the aeration room was previously sterilized with pure EO.

C.5.3 Test Results

Six of the eight sets of grab samples were used to determine the control device efficiency. From the results of the GC analysis provided in the test report the efficiency of the control device was determined to be 99.9+ percent for each of the tests performed. However, these efficiencies are based on EO concentration only and do not reflect the mass of EO entering and exiting the control device. Also, the supporting information provided with the test report is very limited and does not substantiate the 99.9 percent claimed.

Other uncertainties exist in this test report. In all of the downstream grab samples, the EO concentration was determined to be zero (instead of the lower detection limit of the FID). Also, the control inlet EO concentrations are high (10 ppm minimum) for aeration room emission concentrations which typically tend to have an EO concentration of less than 2 ppm.⁷

C.6 REFERENCES

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7. Memorandum. deOlloqui, V., MRI, to Commercial Sterilization Files. Responses to the July 1988 Section 114 Letter. August 22, 1990.

APPENDIX D.

EMISSION MEASUREMENT AND CONTINUOUS MONITORING

APPENDIX D.

EMISSION MEASUREMENT AND CONTINUOUS MONITORING

D.1 METHODS FOR DETERMINING ETHYLENE OXIDE EMISSIONS FROM ETHYLENE OXIDE STERILIZERS EQUIPPED WITH CONTROL DEVICES

Since the early 1980's, concern about the toxicity of ethylene oxide (EO) has spurred the development of methods to accurately measure emissions from sterilizing units that use EO as a sterilant. The U. S. Environmental Protection Agency (EPA), the California Air Resources Board (CARB), manufacturers of EO control devices, and EO sterilizer operators have independently moved toward developing such a method by conducting tests of emission control technologies. The methodologies used in several of these tests are summarized in the following sections. Test methods used to evaluate dilute acid hydrolytic EO scrubbing units are discussed in Reports 1 through 6, and test methods used to evaluate catalytic oxidation units are discussed in Reports 7 through 9. Report 10 is a summary of CARB Method 431.

The reports summarized below were generated by control device vendors gathering data to support efficiency claims, purchasers of control devices to either verify the manufacturer's claims or to comply with State regulations, or by EPA in support of method and standard development. These reports are referenced fully in Section D.4.

D.1.1 Report 1

In this test effort,¹ dilute acid hydrolytic scrubber efficiencies were determined using (1) calculated values for EO emissions vented to the scrubber (inlet) and (2) measured values for EO emissions exhausted from scrubber (outlet). Sampling was

performed over the entire evacuation cycle, which included the initial evacuation and four air washes.

D.1.1.1 Determination of EO Mass Vented to the Scrubber.

The mass of EO vented from the sterilizer to the scrubber was calculated by subtracting the residual mass of EO left in the chamber from the mass of EO charged to the chamber. The mass of EO charged to the chamber was determined by weighing the charging cylinder prior to and after chamber charging. Residual EO concentrations were measured after the sterilization cycle was complete using the following procedure: a diaphragm pump was used to remove a slipstream of gas through a heated Teflon™ line, which was analyzed using a gas chromatograph (GC) equipped with a thermal conductivity detector (TCD). The residual EO mass was calculated based on the chamber volume, temperature, pressure, and the residual EO concentration.

D.1.1.2 Determination of EO Mass Emitted from the Scrubber.

The mass of EO emitted from the scrubber was calculated from repeated measurement of the EO concentration and volumetric flow rate found in the scrubber exhaust. Ethylene oxide concentrations were determined by removing a slipstream of exhaust gas through Teflon™ tubing using a diaphragm pump. A sample of the slipstream was analyzed once every 3 minutes throughout the sterilization cycle using a GC equipped with a flame ionization detector (FID).

The volumetric flow rate of the exhaust gas was measured once each minute throughout the sterilization cycle using an orifice meter installed in the exhaust stack. The gas flow rate changed continuously during the exhaust cycles.

Ethylene oxide concentrations and volumetric flow rate data were then plotted for the initial exhaust and subsequent air wash cycles. Mass emissions of EO were calculated for each exhaust cycle and totalled. Control device efficiency was determined based on the calculated total emissions to the scrubber and measured total emissions from the scrubber.

D.1.1.3 Results. The results of three scrubber efficiency tests performed while a 12/88 mixture of EO and

dichlorodi-fluoromethane was used as a sterilant showed an average EO removal efficiency of 99.1 percent. Removal efficiencies ranged from 98.7 to 99.4 percent. More than 78 percent of the total EO was emitted during the first exhaust cycle.

A single scrubber efficiency test was performed using 100 percent EO as a sterilant. This test demonstrated a removal efficiency of 99.998 percent. Due to technical problems, data for the initial evacuation and the first air wash cycles were not available; thus, the reported amount of 0.00105 pound of EO exhausted was determined from measurements of subsequent air washes.

D.1.2 Report 2

D.1.2.1 Methodology. Report 2 discusses the test methods and results of three efficiency test runs performed on a dilute acid hydrolytic scrubber.² During testing, the sterilizer chamber was empty of product, and 100 percent EO was used as the sterilant. The weights of EO entering and leaving the scrubber were determined by continuously measuring the total volumetric gas flow rate at both the inlet and outlet of the scrubber with orifice meters. Sampling was performed over the entire evacuation cycle, which included the initial evacuation and two air wash cycles. The inlet EO mass was calculated using the difference by weight of the EO supply cylinders and residual EO left in the chamber (see Section D.1.1). However, because it was unclear exactly how residual chamber concentrations were determined, the calculation method will not be discussed.

D.1.2.2 Determination of EO Mass at the Inlet and Outlet of the Scrubber. Samples were withdrawn continuously from the two locations through heated Teflon™ lines using Teflon™-lined pumps. Slipstreams of gas were sampled with gas sampling valves at approximately 1-minute intervals into two GC's. A GC/TCD was used to measure the inlet slipstream and a GC/FID was used to measure the outlet slipstream.

Volumetric flow rate measurements were performed at both sampling locations. Two orifice meters of different sizes were

used at each location to supply flow measurements over the range of expected velocities.

D.1.2.3 Results. The three scrubber performance tests yielded an average removal efficiency of 99.988 percent by weight, with individual values ranging from 99.986 to 99.989 percent. The EO in the initial evacuation accounted for 20 percent or less of the total mass of EO emitted during the sterilization cycle.

D.1.3 Report 3

D.1.3.1 Methodology. In this test program, dilute acid hydrolytic scrubber efficiencies were determined using calculated and measured inlet values for the EO emissions vented to the scrubber and measured values for the EO emissions exhausted from the scrubber.³ Sampling was performed over the entire evacuation cycle, which consisted of the initial evacuation and six air washes. This report compared the "throughput" and "recovery" methods of calculating dilute acid hydrolytic scrubber efficiency (see Section D.1.3.3). Data from 10 test runs were reported. Four test runs were conducted with an empty chamber. All runs used 12/88 as the sterilant.

D.1.3.2 Determination of EO Mass at the Inlet and Outlet of the Scrubber. The concentration of EO entering and leaving the scrubber was measured semicontinuously at the inlet and outlet with a GC/FID. Sample gas was continuously removed from the sampling locations and analyzed at 4-minute intervals. The volumetric flow rate at the outlet of the control device was measured by a vane anemometer in series with orifice plates; the flow rate at the inlet was calculated as discussed below.

D.1.3.3 Efficiency Determinations. The throughput efficiency was calculated using measured EO emissions from the inlet and outlet of the scrubber. Ethylene oxide concentration was measured at the inlet by GC/FID, and inlet volumetric flow rates were calculated using the chamber volume and chamber pressures and temperatures.

The recovery method calculated EO control efficiency based on the weight of EO charged to the sterilization chamber. The EO

charge cylinder was weighed prior to and after charging the chamber, and the weight of EO charged was determined by the difference. The measured outlet EO emissions were used to calculate the recovery efficiency.

D.1.3.4 Results. Only the results for the empty chamber tests will be discussed since tests where the sterilization chamber was loaded with product showed similar removal efficiencies. Throughput efficiencies for the empty chamber tests ranged from 99.82 to 99.98 percent. Recovery efficiencies for the empty chamber tests ranged from 99.90 to 99.97 percent. A one-way analysis of variance (ANOVA) performed on data from the empty chamber tests showed no difference between the recovery method and the throughput method in determining control efficiency.

D.1.4 Report 4

D.1.4.1 Methodology. This report focused on several issues raised by the testing described in Report 3.⁴ The first issue concerned the stability of EO samples in 1-liter (L) (0.264 gallons [gal]) polyvinylfluoride gas bags, 5-milliliter (mL) (0.3 cubic inches [in^3]) gas-tight syringes, and evacuated aerosol cans. The second issue investigated was EO concentration profiles plotted at 1-minute intervals throughout the sterilization cycle using both pure EO and 12/88 mixtures. The third issue was the evaluation of various analytic columns.

The sampling and analytical methods reported varied slightly from those in Report 3. Scrubber exhaust samples were removed from the exhaust stack through a heated Teflon™ line with a diaphragm pump. Samples were placed into 1-L polyvinyl fluoride bags, 5-mL gas-tight syringes, or evacuated aerosol cans.

The linearity, efficiency, resolution, retention time, sample stability, and limits of quantitation and detection were evaluated for three columns.

D.1.4.2 Results. Report 4 concludes that a 5 percent fluorinated oil column is adequate for measuring percent levels of EO and dichlorodifluoromethane, the levels expected at the exhaust of an uncontrolled sterilizer or the inlet of a scrubber.

A 1 percent polyethylene glycol and substituted terephthalic acid column is recommended for measuring part-per-million-by-volume (ppmv) levels of EO, the levels expected at the outlet of a scrubber. The report recommends that a 3-percent polyethylene glycol and substituted terephthalic acid column operated at 45°C (116°F) be investigated for quantifying sub-ppm levels of EO, the levels expected in ambient air at sterilization facilities.

The stability of 12/88 and 100 percent EO samples in Tedlar™ bags were investigated by measurement at time zero and selected intervals thereafter. Both types of samples were not stable over a 4-day period; concentrations of the 12/88 mixture differed by 23 to 96 percent, while the concentrations of the 100 percent EO differed by 15 to 30 percent. Only the 12/88 samples were analyzed at a shorter time interval. After 1 day, the 12/88 mixture concentrations differed 3 to 27 percent from those at time zero, which indicated poor stability.

Aerosol cans containing 100 percent EO were analyzed at time zero and 4 days later. Over this period the EO concentrations differed an average of 15 percent (range +2.82 to -44.6). Syringe samples were analyzed at time zero and after 4 days and were also not found to be stable. The percent difference in concentration for both the 100 percent EO and 12/88 mixtures averaged 23 percent.

Concentration profiles showed that EO concentrations in sterilizer exhaust increased linearly between 5 and 13 minutes after the start of the cycle, reached a plateau between 13 and 20 minutes, and dropped off after 20 minutes.

D.1.5 Report 5

D.1.5.1 Methodology. Report 5 addresses six test runs conducted at a scrubber exhaust flow rate of 1.8 cubic meters per minute (m^3/min) (66 cubic feet per minute [ft^3/min]) and three conducted at a scrubber exhaust flow rate of 2.8 m^3/min (100 ft^3/min).⁵ Flow through the scrubber appears to have been set for this test program, as no record of volumetric flow rate measurement is present in the report. A 12/88 EO mixture was

used as the sterilant. The number of evacuations tested in each sterilization cycle was not reported.

Scrubber inlet samples were acquired three times during the entire test effort. Grab samples were taken using polyvinyl-fluoride bags and analyzed in GC/FID, as described below. The EO concentrations of the three grab samples were 15.0, 27.4, and 29.0 percent. The average concentration of the three samples (23.8 percent) was used as the scrubber inlet concentration. The removal efficiencies were calculated using the average inlet concentration and the peak outlet concentrations.

The scrubber outlet emissions were sampled using a heated Teflon™ line and a Teflon™-coated pump. Grab samples were removed from the sample line at approximately 2-minute intervals using a syringe. The remaining sample passed into an infrared (IR) spectrometer. The syringe samples were analyzed by a standardized GC/FID. The IR spectrometer used to provide a second measure of scrubber outlet EO concentrations was set at a wavelength of 3.3 microns to reduce interferences.

D.1.5.2 Results. All of the efficiency results were based on the average measured inlet concentration of 23.8 percent EO and the maximum outlet EO concentration measured for a particular sterilization cycle. The variation in EO inlet concentrations indicates poor precision in determining scrubber inlet EO concentrations by this method. The efficiency determined by using the GC averaged 99.26 percent (99.16 to 99.32 percent range). The average efficiency determined by using IR spectroscopy was 99.16 percent (99.03 to 99.21 percent range).

D.1.6 Report 6

D.1.6.1 Methodology. In Report 6, EO removal efficiencies for a dilute acid hydrolytic scrubber were calculated by measuring EO concentrations at the scrubber inlet and outlet, scrubber outlet volumetric flow rates, and scrubber inlet and outlet temperatures.⁶ Testing was performed under laboratory conditions on a full-scale acid-hydrolysis system. Each test cycle included two evacuations and use of a 12/88 mixture of sterilant.

Inlet and outlet EO concentrations were measured by GC/FID. The sample gas was removed from both ducts via Teflon™ tubing. Grab samples were removed from the tubing with a syringe every 40 seconds. Volumetric flow rate was measured at the scrubber outlet location using a calibrated dry test meter. Scrubber inlet flow rate was calculated by adding the EO volumetric flow rate. Using the measurements of EO concentration, temperature, and flow rate, the EO removal efficiency was calculated based on the total amount of EO that entered and left the scrubber system.

Four runs were performed on actual sterilizer exhaust, and three were performed with simulated sterilizer exhaust. For the simulated exhaust, a 12/88 mixture of sterilant gas was injected into the ductwork leading to the scrubber.

D.1.6.2 Results. Destruction efficiencies for the runs with actual exhaust ranged from 99.995 to 99.998 percent. The destruction efficiency for the EO injection runs averaged 99.999 percent. It was noted that of the EO charged to the sterilizer chamber, 25 to 56 percent was exhausted to the scrubber during the initial evacuation. A more accurate inlet flow rate determination would provide more representative efficiency results.

D.1.7 Report 7

D.1.7.1 Methodology. Report 7 describes the method used to determine the EO removal efficiency of a catalytic oxidation unit controlling aeration room emissions.⁷ The sterilant was 100 percent EO, and six test runs were performed. Presurvey testing was conducted where a 12/88 mixture was used and four runs were performed.

D.1.7.2 Determination of EO Mass at the Inlet and Outlet of the Scrubber. The volumetric flow rates of the inlet and outlet sample gas streams was measured by traversing the ducts with a standard pitot tube according to EPA Methods 1 and 2 (40 CFR Part 60, Appendix A). Gas temperature and relative humidity were measured at the same locations.

Inlet and outlet grab samples were collected simultaneously in polyvinylfluoride gas bags using heated Teflon™ sampling lines

and Teflon™-coated pumps. The bag samples were analyzed by GC/FID within 20 hours of sample acquisition.

D.1.7.3 Results. The concentrations at the control device outlet were below the detection limit of the GC, and EO removal efficiencies were assumed to be greater than 99.9 percent. The EO removal efficiencies determined using presurvey samples ranged from 99.4 to 99.6 percent. The report speculated that the variation in efficiencies was due to the type of sterilant used and differences in chamber operating parameters.

D.1.8 Report 8

D.1.8.1 Methodology. Report 8 presents the results of seven efficiency test runs performed on a catalytic oxidation system used to control EO emissions from a sterilizer.⁶ Three test runs were performed on actual sterilizer exhaust and four test runs were conducted while EO cylinder gas was injected into the ductwork leading to the catalytic oxidation system inlet. Each test cycle included two evacuations, and the sterilant was a 12/88 mixture.

The gas stream entering the catalytic oxidation system was continuously monitored for EO using a total hydrocarbon analyzer equipped with an FID. Additional inlet EO concentration measurements were made on grab samples using GC. An EO concentration profile for the catalytic oxidizer outlet was derived from GC analysis of grab samples. The sample gas streams were removed at the catalytic oxidizer inlet and exhaust and sampled using Teflon™ tubing and a pump. Grab samples were removed from this tubing with gas-tight syringes at 40-second intervals during the exhaust cycle.

Flow rate measurements were performed at the catalytic oxidizer inlet using a standard Pitot tube. A traverse of the duct was performed, and the volumetric flow rate was measured subsequently at a point of average velocity of the traverse. The outlet flow rate was assumed to be equal to the inlet flow rate. This sampling point was located after ambient air was added to the unit. Although the flow rate exhausted from the sterilizer diminished over each evacuation cycle, the flow at the catalytic

oxidizer test point did not change significantly. In comparison to dilute acid hydrolytic scrubbers, catalytic oxidizers exhibit relatively stable inlet and outlet flow rates because ambient air is added prior to the unit. Catalytic oxidizer inlet and outlet gas temperatures were also monitored.

Using the measurements of EO concentration (inlet and outlet), temperature, and flow rate, the EO removal efficiency was calculated based upon the total mass of EO that entered the catalytic oxidizer and the total mass of EO that left the unit.

D.1.8.2 Results. The EO removal efficiencies for the sterilizer discharge tests ranged from 99.16 to 99.40 percent. Removal efficiencies for the duct injection tests ranged from 99.89 to 99.98 percent

D.1.9 Report 9

D.1.9.1 Methodology. Report 9 describes the methods used to determine the EO removal efficiency of a catalytic oxidation unit used to control aeration room exhaust.⁸ Since EO concentrations to the catalytic oxidizer were approximately 2 ppmv under normal operating conditions, pure EO cylinder gas was added at the inlet duct to yield EO concentrations of 100 ppmv. Gas samples were acquired at the inlet to the control device, after each of the three catalyst beds, and at the exhaust stack. A volumetric flow rate was reported for the exhaust stack, but no mention was made regarding the methods used to acquire these data.

Samples were collected using hydrogen bromide (HBr)-coated charcoal tubes over a period of 24 hours at each of the five locations described above. Each sampling train consisted of a Teflon™ tube connected to two or more charcoal tubes in series, connected to a sampling pump. Inlet sampling was conducted for a 20-minute period every 2 hours for the entire 24-hour test run. Samples were recovered from the charcoal tubes in a manner similar to NIOSH Method 1614, and the analysis was performed by GC/FID.

D.1.9.2 Results. The annual EO emissions to the atmosphere were calculated to be <0.043 kilograms per year (kg/yr)

(<0.095 pounds per year [lb/yr]), based on a volumetric flow rate of 19 actual m³/min (694 actual cubic feet per minute [aft³/min]). The EO removal efficiency of the catalytic oxidizer was calculated to be >99.99 percent.

As the methodology for determining volumetric flow rate was not presented in this report, this discussion is limited to the sampling and analytical methodology, specifically, the use of HBR-coated charcoal tubes in conjunction with an integrated sampling rate.

Direct GC/FID analysis of EO gas samples (Reports 1 through 9) yields a detection limit of approximately 1 ppmv. Use of the HBR-coated charcoal tubes allows concentration of the EO sample and a consequent decrease in the detection limit for EO in the gas stream to 3 parts per billion by volume (ppbv). This permits more accurate quantitation of EO concentrations in the diluted exhaust gas streams from catalytic oxidation emission control devices.

D.1.10 Report 10

Report 10 is not a test report but rather a summary of CARB Method 431, "Determination of Ethylene Oxide Emissions From Stationary Sources."⁹ Method 431 was based on the same methodologies described in Reports 3 and 4 (References 1 and 2), with the exception that turbine (vane anemometer) or Roots-type flow meters rather than orifice meters are used to determine volumetric flow rate. Emission testing is performed on sterilizers containing normal product loads. Volumetric flow rate and EO concentrations of the vent gas are measured repeatedly for the duration of the sterilization cycle. Total emissions are calculated from curves representing flow and concentration versus time.

As mentioned above, the CARB method requires the use of vane anemometers or Roots-type meters to measure volumetric flow rate; these are certified to 1.5 percent accuracy by the manufacturer. Two or more meters may be installed in parallel if necessary to achieve this requirement over the entire expected range of flow rates. A valve is used to switch between the two meters as flow

rates change. Also required are measurements from temperature and pressure sensors to convert the measured flow rate to standard temperature and pressure conditions.

The sample gas is continuously removed from the exhaust stack via heated fluoroethylene or polytetrafluoride sample line at a rate in excess of 1 L/min (0.036 ft³/min). A slipstream is removed from this line and directed to the GC sampling loop via a gas sampling valve. The sample is analyzed as frequently as possible (1-minute intervals for 100 percent EO and 3- to 4-minute intervals for EO mixtures). Sample loop pressure, sample flow rate, and slipstream flow rate must be measured/recorded during this process. Excess sample is bubbled through a sulfuric acid solution prior to discharge. A GC is required for the analysis.

Also suggested are calibration gas concentrations for both percent and ppm level analysis. Some lateral freedom is given with respect to calibration gas makeup and concentration. It is required that a similar midrange audit standard be used to verify calibration gas composition and GC performance. Audit standards and calibration gases must be supplied and certified by separate suppliers.

Additional guidelines for a pretest site survey, GC preparation, flow metering, sample train setup and operation, data reduction, and integration of the mass flow rate curve are also provided.

D.2 MONITORING SYSTEMS AND DEVICES

The following parameters may be monitored to indicate proper control device operation. All monitoring equipment should be installed, calibrated, maintained, and operated according to the manufacturer's specifications.

The following parameters indicate proper control device operation for counter-current packed scrubber and reaction/detoxification towers and thus will be monitored:

1. The EO charged to the sterilizer by weighing cylinders or by monitoring liquid flow rate using a rotameter or orifice; and

2. The ethylene glycol concentration in the scrubber liquor using liquid level indicators or specific gravity detectors in the tank. If the ethylene glycol concentration exceeds 60 weight percent, the scrubber liquid must be changed.

The following parameters indicate proper control device operation for catalytic oxidation and should be monitored:

1. The gas temperature both upstream and downstream of the catalyst bed using a device that continuously measures these temperatures while the control device is in operation; and

2. The amount of diluent air using a Pitot tube or other flow measurement device.

Proper operation of a flare is indicated by the continuous presence of a flame. Therefore, a heat-sensing device, such as an ultra-violet beam sensor or thermocouple, shall be installed at the pilot light to indicate the continuous presence of a flame.

D.3 PERFORMANCE TEST METHODS

D.3.1 Test Method Background

The EPA EO test method will reference the EPA Method 2 series and EPA Method 18 (40 CFR 60, Appendix A) as its base. Methods 2, 2A, 2C, and 2D apply for measuring flow rates from control device exhaust. The particular method applied depends on the size of the duct. If orifice meters (or a similar device) are used, it may be necessary to install more than one size in series to measure over flow rate variations.

Method 18 applies for measuring EO concentrations entering and exiting both catalytic oxidizers and dilute acid hydrolytic scrubbers. Using appropriate chromatographic columns and temperature programming eliminates interferences from dichlorodifluoromethane and potential EO degradation products.

D.3.2 Test Method Advantages/Disadvantages

Listed below is a summary of the different methodologies that have been addressed in D.1 and the advantages and disadvantages of each technique. These factors have been considered in developing the EPA test method.

D.3.2.1 Calculation of Inlet Mass. To determine the inlet mass of EO emissions entering the control device by calculation, the amount of sterilant entering the control device must be measured by weighing the cylinder before and after charging the sterilizer. The residual EO left in the chamber can be determined using the ideal gas law and would be subtracted from the cylinder weight to calculate the inlet mass.

The principal advantage of this technique is that it avoids the hazards of handling high levels of EO. The principal disadvantage is that a system leak will diminish the accuracy. However, a leak is unlikely since sterilizer sources must also comply with health and safety rules requiring continuous monitoring of worker exposure to EO.

D.3.2.2 Measuring the Inlet Mass or Outlet Mass. Direct measurement of the outlet mass emission rates requires determination of the flow rate and EO concentration. Direct measurement of the inlet mass emission rate would require an additional set of equipment and would have the additional hazards of handling high levels of EO. However, direct measurement would eliminate the potential for bias created by a leak in the system.

The EO concentration can be determined by semicontinuous sampling with a GC. However, the elution time for EO mixtures such as 12/88 is 3 minutes, which is not frequent enough to define the emission profile of a sterilizer. One-minute analyses are possible for pure EO. Grab samples may be taken at any interval and later analyzed by GC to better define the emission profile. However, the stability of EO in bags, syringes, and vacu-samplers needs additional investigation.

Removing the sample gas through a heated, inert sampling line and analyzing it immediately eliminates the potential for sample degradation and condensation.

An orifice meter is capable of providing continuous volumetric flow rate information. It is appropriate for measuring volumetric flow rate in a system where flow rates vary rapidly. Multiple orifice meters can be used to cover a wide range of flow rates.

The presence of other components in the vent gas stream creates two problems. First, components eluting near the EO peak may create confusion in identifying and quantitating the EO peak. Second, components that elute after EO and dichlorodifluoromethane extend the analysis time and decrease the number of on-line samples that can be analyzed.

D.3.2.3 Efficiency Determinations. An efficiency determination based on the initial evacuation of a sterilizer does not necessarily evaluate the scrubber efficiency during subsequent air washes. Integrating the EO concentration curve instead of using a peak concentration value is more representative of overall efficiency; using the peak concentration will negatively bias the results.

D.4 REFERENCES

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8. Engineering Science. Report of Air Pollution Source Testing conducted at IOLAB Corporation. December 7, 1988.
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APPENDIX E.
SUPPLEMENTAL INFORMATION TO THE COST ANALYSIS

APPENDIX E.

SUPPLEMENTAL INFORMATION TO THE COST ANALYSIS

This Appendix contains supplemental information used in analyzing costs associated with the regulation of ethylene oxide (EO) commercial sterilization facilities. . Included in this appendix are: (1) costs for acid-water scrubbers (Section E.1); (2) sample calculations of the equations used to develop capital and annual costs for acid-water scrubbers (Section E.2); (3) aeration room cost analysis (Section E.3); (4) capital and annual control costs for the sterilizer chamber, chamber exhaust, and aeration room vent(s) at an example facility (Section E.4); (5) a breakdown of manifolding costs for these three vents (Section E.5); and (6) the cost indices and conversion factors used to convert costs to fourth quarter 1987 dollars (Section E.6).

E.1 COSTS FOR ACID-WATER SCRUBBERS

TABLE E-1. COST OF DAMAS SCRUBBER MODELS (F.O.B.)^{1,2}
(4th Quarter 1987 Dollars)

Model No.	Chamber size, m ³ (ft ³) ^a	Flow rate (acfm)	Conversion capacity of scrubber, kg (lb) of EO	Automated scrubber cost, \$	Cost of explosion-proof valves for scrubber, \$ ^b
25	< 1.4 (<50)	40	227 (500)	8,980	N/A ^c
50	1.4 to 2.8 (50 to 100)	60	454 (1,000)	13,500	N/A ^c
100	< 11.3 (<400)	50-100	908 (2,000)	46,800	12,800
200	11.3 to 17.0 (400 to 600)	> 100-200	1,816 (4,000)	67,700	13,800
300	17.0 to 22.7 (600 to 800)	> 200-300	2,724 (6,000)	88,500	14,900
400	22.7 to 45.3 (800 to 1,600)	> 400	3,632 (8,000)	98,900	16,000
500	45.3 to 56.6 (1,600 to 2,000)	> 500	4,540 (10,000)	141,000	18,100
600	> 56.6 (> 2,000)	> 600	5,448 (12,000)	156,000	19,100

^aThe size of sterilization chamber that can be served by the model number, assuming the smallest appropriate vacuum pump is used.³

^bExplosion-proof valves are necessary if the sterilization chamber that is vented to the scrubber uses a gas mixture greater than 20 percent by weight EO.^{4,5}

^cPrice of explosion-proof valves included in cost of these models.

^dAcfm actual cubic feet per minute.

TABLE E-2. CAPITAL AND ANNUALIZED COSTS OF INSTALLING SCRUBBERS¹
(4th Quarter 1984 Dollars)

Item	Cost
A. CAPITAL COSTS^a	
<u>Installed equipment costs</u>	
Automated scrubber	N/A ^b
Explosion-proof valves for scrubber	b
Chlorine filter house	b
Purchased equipment costs, total	b
Installation of scrubber	b
Installation of chlorine filters	b
Taxes: 5 percent of equipment cost	b
Freight: 5 percent of equipment cost	b
Vacuum pump ^c	19,700
Manifolding of chambers (includes check valve)	b
Total capital costs, 1984 dollars	19,700
B. ANNUALIZED COSTS^a	
<u>Direct operating costs</u>	
Labor ^d	b
Materials	
50 percent H ₂ SO ₄	
50 percent NaOH	b
Chlorine filters	b
Taxes: 5 percent of materials cost	b
Freight: 5 percent of materials cost	b
Compressed air	b
Disposal of ethylene glycol	b
<u>Indirect operating costs</u>	
Overhead: 0.80 x labor	b
Property tax, insurance, and administration ^e	788
Capital recovery costs ^c	3,210
Total annualized costs	4,000
C. COST EFFECTIVENESS	
Reduce, Mg EO yr	43.56
Cost effectiveness, 1984, \$/Mg EO	92

^aRounded to three significant figures.

^bNot applicable.

^cFour vacuum pumps at \$4,935 each.

^dLabor was calculated for 0.25 person-hours/shift, 3 shifts/d, 365 d/yr for system inspection and 16 person-hours for each regeneration of the scrubber at \$11.60/person-hour.

^eCalculated as 4 percent of total capital cost.

TABLE E-3. DATA USED TO CALCULATE SCRUBBER EQUIPMENT
CAPITAL COSTS¹
(4th Quarter 1987 Dollars)

Item	Cost factor
Automated scrubber	--a
Explosion-proof valves for scrubber	--a b
Chlorine filter house	(\$41.50 each) x (No. of tanks) ^c
Scrubber installation	50 percent of scrubber cost
Chlorine filter installation	(\$20.00) x (No. of tanks) ^c
Taxes	5 percent of total equipment cost
Freight	5 percent of total equipment cost
Vacuum pump(s)	\$5,170 per pump
Manifolding of chambers	--d
Check valve	--e

^aFunction of chamber size (see Section E.1).

^bExplosion-proof valves are necessary if the chamber that is vented to the scrubber uses a gas mixture greater than 20 percent (by weight) EO. (See Section E.1).

^cNumber of scrubber tanks required = scrubber conversion capacity divided by the conversion capacity of one tank (2,000 pounds of EO).

^dSee Section E.5.

^eSee Table E-4.

TABLE E-4. CAPITAL COST OF CHECK VALVE FOR CHAMBER

Cost item	Cost 1987, \$	Richardson reference ²
Swing check valve	367	15-43, p. 31
Labor hours to install	1.1	15-43, p. 31
Labor costs at \$21.47/labor hour	24	15-0, p. 2
Overhead costs at \$13.31/labor hour	15	1-0, p. 5
Total direct costs	391	
Administration: 10 percent of total direct costs	39	1-0, p. 5
Taxes: 5 percent of equipment cost	18	1-0, p. 6
Total indirect costs	72	
Total installed cost	463	
Annualized capital recovery cost ^a	75	GARD, p. 3-18 ³

^aCalculated as $0.16275 \times (\text{total installed cost})$, for an interest rate of 10 percent and a 10-year recovery period.

TABLE E-5. DATA USED TO CALCULATE CONTROL DEVICE ANNUALIZED COSTS¹
(4th Quarter 1987 Dollars)

Item	Cost factor
<u>Direct operating costs</u>	
Labor	$\$3,188 + (\$11.65) \times (16 \text{ person-hours}) \times (\text{No. of scrubber regenerations})^a b$
Materials:	
50 percent H_2SO_4	$(\$0.0702/\text{lb}) \times (594 \text{ lb/drum}) \times (\text{No. of drums required}) \times (1.15)^{c-e}$
50 percent NaOH	$(\text{Cost/lb}) \times (700 \text{ lb/drum}) \times (\text{No. of drums required}) \times (1.15)^{c, f, g}$
Chlorine filters	$(\$15/\text{filter}) \times (\text{No. of tank regenerations}) \times (\text{No. of tanks})^{c h}$
Taxes	5 percent of materials cost
Freight	5 percent of materials cost
Compressed air	0 ⁱ
Disposal of ethylene glycol	-j
<u>Indirect operating costs</u>	
Overhead	$(0.6) \times (\text{labor costs})$
Property tax, insurance, and administration	4 percent of total capital costs
Capital recovery costs	$(0.16275) \times (\text{total capital costs})^k$

^aNumber of scrubber regenerations = amount of EO to be treated divided by the conversion capacity of the scrubber (See Example Calculation No. 6 in Section E.2)

^bThe \$3,188 is for visual inspection of the system 15 minutes per shift, 3 shifts per day, 365 days per year at \$11.65/person-hour. It was assumed that each regeneration of the scrubber solution would require two people at 8 person-hours each, independent of scrubber size.

^cNumber of scrubber tanks = scrubber conversion capacity divided by the conversion capacity of one tank (2,000 pounds of EO). Number of tank regenerations = number of scrubber regenerations multiplied by the number of scrubber tanks.

^dEach tank regeneration requires one 55-gallon drum of 50 percent H_2SO_4 .

^eFifteen percent extra is allowed for spillage.

^fEach tank regeneration requires 250 pounds of NaOH for neutralization.

^gCost basis for 50 percent NaOH (350 pounds NaOH per drum):

^fNo. of drums > 9, cost/lb = \$0.0110.

If No. of drums = 3 to 9, cost/lb = \$0.0802.

If No. of drums < 2, cost/lb = \$0.0752.

^hEach chlorine filter can dechlorinate approximately 200 gallons (one tank) of H_2O ; replace filter at each tank regeneration.

ⁱThe cost of 10 seconds of in-house compressed air per cycle is considered negligible.

^jUnit cost of disposal was calculated by multiplying the total number of tank regenerations by the weight of a tank at regeneration, approximately 4,845 lb (see Example Calculation No. 3 in Section E.2).

If the total weight < 42,000 lb, disposal cost = (weight) \times (\$0.110/lb).

If the total weight \geq 42,000 lb, disposal cost = (weight) \times (\$0.068/lb).

^kAssumes an interest rate of 10 percent and a 10-year recovery period.

TABLE E-6. MISCELLANEOUS OPERATING COSTS¹

Item description	Cost, 1987 \$
Operating materials	
1. 50 percent H ₂ SO ₄ , electrolyte-grade	0.0702/lb
2. 50 percent NaOH, industrial grade:	
<2 drums	0.110/lb
3-9 drums	0.0802/lb
>9 drums	0.0752/lb
3. Chlorine filters:	
Filter housing	41.50 each
Filter	15.00 each
Installation	20.00 each
Shipping charges for waste disposal	
Weight of solution for disposal:	
<42,000 lb (drums)	0.110/lb
≥42,000 lb (bulk)	0.068/lb

TABLE E-7. COST OF Eto ABATOR™ CATALYTIC
OXIDIZERS (F.O.B.)¹⁻³
(1987 Dollars)

Design flow rate, m ³ /min (ft ³ /min)	Cost, \$ ^{a b}
28 (1,000)	48,000
84 (3,000)	81,000
168 (6,000)	112,000
252 (9,000)	148,000
336 (12,000)	189,000

^aCosts in 1989 dollars were corrected to 1987 dollars using the "Chemical Engineering" Plant Cost indices.

^bCost of replacement catalyst is \$1,500/cell in 1989 dollars, or approximately \$1,240/cell in 1987 dollars.^{2,4,5}

E.1 COSTS OF ACID-WATER SCRUBBERS

REFERENCES

1. Telecon. Srebro, S., MRI, with D. Smith. Damas Corp. June 20, 1986. Discussion about costs of the Damas Tri-Phase ethylene oxide scrubbers.
2. Telecon. Srebro, S., MRI, with D. Smith. Damas Corp. December 12, 1989. Discussion about costs of Models 25 and 50 Damas acid/water scrubbers.
3. Beall, C., Meeting Minutes: Damas Corp. and Johnson & Johnson. Midwest Research Institute. Raleigh, NC. April 30, 1986. 9 p.
4. Telecon. Glanville, J., MRI, with C. Woltz. Union Carbide, Inc. February 10, 1987. Discussion about flammability of EO mixtures.
5. Telecon. Srebro, S., MRI, with M. Popescu. Johnson & Johnson International. June 16, 1986. Discussion about the Damas Tri-Phase ethylene oxide scrubbers.

E.2 SAMPLE COST CALCULATIONS FOR ACID-WATER SCRUBBERS

E.2 SAMPLE COST CALCULATIONS FOR ACID-WATER SCRUBBERS

	Sterilization chambers at the facility				
	No. 1	No. 2	No. 3	No. 4	No. 5
Size, m ³ (ft ³)	19 (667)	19 (667)	34 (1,200)	37 (1,334)	37 (1,334)
Gas type	100	100	12/88	100	100
EO USE, kg (lb)	12,700 (28,000)	12,700 (28,000)	540 (1,200)	21,000 (46,000)	21,000 (46,000)
EO-EMIT, kg (lb)	12,100 (26,600)	12,100 (26,600)	520 (1,140)	19,800 (43,700)	19,800 (43,700)
MEO-EMIT, Mg (tons)	12.07 (13.52)	12.07 (13.52)	0.52 (0.58)	19.82 (22.20)	19.82 (22.20)

Facility totals	
EO-FAC, kg (lb)	64,310 (141,740)
MEO-FAC, Mg (tons)	64.30 (72.02)
EO-TOT, kg (lb)	67,695 (149,200)
MEO-TOT, Mg (tons)	67.7 (74.6)
CON-EM, Mg (tons)	0.64 (0.70)
REDUCE, Mg (tons)	63.66 (70.15)

1. The size, gas type, and EO use are those for an actual commercial sterilization facility represented in the EPA data base. (See Section 3.1 of this report for a description of how this data base was developed.) The other values were calculated using the following assumptions:

a. EO-EMIT (lb) = EO (lb) emitted annually from an individual sterilization chamber to the vacuum pump drain and to the atmosphere. As shown in Section 3.4 of this document, sterilizer vent emissions and vacuum pump drain emissions were assumed to be 50 percent and 45 percent of EO use (lb), respectively. Residual EO in the sterilized product prior to aeration was assumed to be 5 percent of EO-USE (lb). This 5 percent of the EO use is not included as part of EO-EMIT (lb).

b. MEO-EMIT (Mg EO) = EO-EMIT (lb)/2,204.6

c. EO-FAC (lb) and MEO-FAC (Mg) are the amount of EO released annually by the facility to the vacuum pump drain and to the atmosphere, i.e., the sum of EO-EMIT and the sum of MEO-EMIT, respectively.

d. EO-TOT (lb) is the total amount of EO (lb) used annually by the facility, i.e., the sum of EO use. $\text{MEO-TOT (Mg)} = \text{EO-TOT (lb)} / 2,204.6$.

e. CON-EM (Mg) is the amount of EO that would be released annually after control, i.e., $\text{MEO-TOT} \times (1 - 0.99) \times 0.95$. Note that the 5 percent residual EO in the sterilized product, which is later released from the aeration room vent, is excluded from this calculated emission estimate.

f. REDUCE (Mg) is the incremental amount of EO that would be reduced if controls are implemented, i.e., $(\text{MEO-FAC}) - (\text{CON-EM})$.

2. For all calculations, a conversion efficiency of 99.0 percent was assumed for the scrubber.

3. Each tank of the scrubber initially holds 0.75 m^3 (198 gal) H_2O and 0.075 m^3 (19.8 gal) H_2SO_4 . The manufacturer recommends that the tank be regenerated (i.e., drained, rinsed, and refilled) after 907 kg (2,000 lb) EO have been treated.

a. 0.075 m^3 (19.8 gal) $\text{H}_2\text{SO}_4 = 1.42 \text{ kg-mole } \text{H}_2\text{SO}_4$ ($\rho = 1.834$; $\text{MW} = 98.08$) $2\text{NaOH} + \text{H}_2\text{SO}_4 \rightarrow \text{Na}_2\text{SO}_4 + 2\text{H}_2\text{O}$; 1.42 kg-mole H_2SO_4 requires 2.84 kg mole NaOH to neutralize. Neutralization will produce 2.84 kg-moles H_2O and 1.42 kg mole Na_2SO_4 . Use 50 percent (w/w) NaOH to neutralize; each 0.21-m^3 (55-gal) drum of 50 percent NaOH weighs 318 kg (700 lb), i.e., 159 kg (350 lb) NaOH ($\text{MW} = 40$); need 2.84 kg-moles or 114 kg (250 lb) NaOH to neutralize.

b. $\text{C}_2\text{H}_4\text{O (EO)} + \text{H}_2\text{O} \rightarrow \text{C}_2\text{H}_4(\text{OH})_2$ (ethylene glycol); 907 kg (2,000 lb) EO = 20.51 kg-moles EO ($\text{MW} = 44.1$).

c. At 99 percent conversion, yield is 20.365 kg-moles or 1.14 m^3 (301 gal) ethylene glycol (EG) ($\text{MW} = 62.07$; $\rho = 1.1088$).

d. At 99 percent conversion, 20.365 kg-moles H_2O have reacted. 41.64 kg moles H_2O originally available ($\text{MW} = 18$; $\rho = 1$); 21.275 kg-moles or 0.38 m^3 (100 gal) H_2O remain unreacted.

e. Weight of neutralized solution per tank: 1.42-kg mole $\text{Na}_2\text{SO}_4 = 202 \text{ kg } \text{Na}_2\text{SO}_4$ ($\text{MW} = 142.04$); 2.84 kg-moles H_2O (from neutralization) = 51 kg (112 lb) H_2O ; 250 lb (113 kg) H_2O = from 50 percent NaOH solution; 0.38 m^3 (100 gal) unreacted H_2O

= 378 kg H₂O (833 lb); 1.14 m³ (301 gal) EG = 1,264 kg (2,786 lb) EG; total wt = 2,008 kg = 4,427 lb.

f. Solution is 63 percent (w/w) EG. Add about 0.19 m³ (50 gal) rinse water for each tank = 189 kg (416 lb); total wt (+ rinse H₂O) = 2,198 kg (4,844 lb); total gal (+ rinse H₂O) = 1.87 m³ (495 gal) = nine 0.21 m³ (55-gal) drums; wt per 0.21 m³ (55-gal) drum = 244 kg (538 lb).

4. Find scrubber model and cost from Table E-1, based on the sum of the volumes of the two largest chambers at the facility:

Chambers 4 and 5 75 m³ (2,668 ft³) Model 600 \$157,500

5. Because at least one chamber uses 100 percent EO, explosion-proof valves are necessary.

6. Find number of regenerations of scrubber required per year:

a. Number of scrubber tanks = scrubber model/100 = 6 (scrubber consists of modular tanks).

b. Conversion capacity of scrubber = (No. of tanks) x 2,000 lb = 12,000 lb.

c. Number of scrubber regenerations = EO-FAC (lb)/12,000, i.e., the amount of EO (lb) to be treated per year divided by the conversion capacity of the scrubber.

141,700/12,000 = 11.81 scrubber regenerations/yr

d. Number of tank regenerations = (No. of scrubber regenerations) x (No. of tanks per scrubber)
= (11.81) x (6) = 70.87.

7. Cost of chlorine filter housing = (41.50) x (No. of tanks) = \$(41.50) x (6) = \$249.

8. Installation costs:

a. Scrubber installation = (0.5) x (cost of scrubber) = \$78,750

b. Chlorine filter housing installation = (20) x (No. of tanks) = \$120.

9. The incremental capital costs of manifolding are presented in Table E-14 of this report.

10. Vacuum pumps. A closed-loop recirculating water vacuum pump is required on each of the five chambers. The cost of modifying the first vacuum pump is included in the cost of the scrubber; the cost of modifying the other four vacuum pumps is \$4,935 each.

11. Calculate direct operating costs:

a. Labor = $3,177 + (11.60) \times (16) \times (\text{No. of regenerations})$.
The \$3,177 is for general inspection of the system
15 minutes/shift, 3 shifts/d, 365 d/yr at \$11.60/person-hour.
For the purposes of these cost analyses, it was assumed that each regeneration of the scrubber would require 2 people at 8 person-hours each, independent of scrubber size. System inspection was also assumed to be independent of scrubber size.

b. Sulfuric acid (50 percent H_2SO_4 -electrolyte grade).
Assumed: 1 55-gal drum of 50 percent H_2SO_4 , i.e., 19.4 gal H_2SO_4 , per scrubber tank.

No. of drums required = No. of tank regenerations = (No. of scrubber regenerations) \times (No. of tanks per scrubber) = 70.87
Cost of acid = (No. of drums) \times (594 lb/drum) \times (\$0.069/lb)

c. Caustic (50 percent NaOH-industrial grade). First, the unit cost of NaOH was calculated.

NaOH required per year = [No. of tank regenerations] \times [NaOH (lb) required per tank] = $70.87 \times 250 = 17,718$ lb/yr

Total drums/yr required by facility = total NaOH (lb)/350 lb per drum; total drums = 50.6

If total drums >9 , cost/lb = 0.0738

If total drums = 3 to 9, cost/lb = 0.0787

If total drums = <2 , cost/lb = 0.108

Cost of caustic = (No. of drums) \times (cost/lb) \times (700 lb/drum)

d. Cost of chlorine filters. Each filter can dechlorinate 200 gal H_2O (or 1 scrubber tank); replace at each scrubber regeneration.

Cost = (No. of scrubber regenerations) \times (No. of tanks) \times (\$15/filter)

e. Disposal. Unit cost of disposal was calculated by multiplying the total number of tank regenerations by the weight of a tank at the time of regeneration, including rinse water (see 3.f).

Total wt = $70.87 \times 4,844 \text{ lb/tank} = 343,943 \text{ lb/yr}$

If total wt < 42,000 lb, disposal cost = wt (lb) x (\$0.096/lb)

If total wt \geq 42,000 lb, disposal cost = wt (lb) x (\$0.059/lb)

f. Compressed air. The cost of 10 seconds of in-house air per cycle was considered negligible and was not computed for these cost analyses.

12. The capital and annualized costs are reported in Tables E-3 and E-5.

REFERENCES

1. Memorandum. Srebro, S., to D. Markwordt. EPA/CPB. Cost Effectiveness of Reducing Ethylene Oxide Emissions from Sterilizer Vents and Associated Vacuum Pump Drains. March 21, 1991.
2. Richardson Engineering Services, Inc. Process Plant Construction Estimating Standards. 1984.
3. Neveril, R., Capital and Operating Costs of Selected Air Pollution Control Systems. GARD, Inc. Niles, IL. Publication No. EPA-450/5-80-002. December 1978.

E.3 AERATION ROOM COST ANALYSIS

TABLE E-8. AERATION ROOM GAS/SOLID REACTANT CONTROL
COST ANALYSIS

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
1.50	1	0	1	0	44200	63600	30000	0.0000202	150000000
2.00	1	0	1	0	44200	63600	30000	0.0000269	110000000
2.98	1	0	1	0	44200	63600	30000	0.0000401	75000000
4.80	1	0	1	0	44200	63600	30000	0.0000647	46000000
6.00	1	0	1	0	44200	63600	30000	0.0000808	37000000
6.00	1	0	1	0	44200	63600	30000	0.0000808	37000000
6.00	1	0	1	0	44200	63600	30000	0.0000808	37000000
6.00	1	0	1	0	44200	63600	30000	0.0000808	37000000
7.50	1	0	1	0	44200	63600	30000	0.0001010	30000000
9.00	1	0	1	0	44200	63600	30000	0.0001212	25000000
12.00	1	0	1	0	44200	63600	30000	0.0001617	19000000
16.80	1	0	1	0	44200	63600	30000	0.0002263	13000000
17.80	1	0	1	0	44200	63600	30000	0.0002398	13000000
27.36	1	0	1	0	44200	63600	30000	0.0003686	8100000
32.40	1	0	1	0	44200	63600	30000	0.0004365	6900000
32.40	1	0	1	0	44200	63600	30000	0.0004365	6900000
32.40	1	0	1	0	44200	63600	30000	0.0004365	6900000
61.34	1	0	1	0	44200	63600	30000	0.0008264	3600000
64.00	1	0	1	0	44200	63600	30000	0.0008622	3500000
64.80	1	0	1	0	44200	63600	30000	0.0008730	3400000
65.00	1	0	1	0	44200	63600	30000	0.0008757	3400000
70.00	1	0	1	0	44200	63600	30000	0.0009430	3200000
93.60	1	0	1	0	44200	63600	30000	0.0012610	2400000
100.80	1	0	1	0	44200	63600	30000	0.0013580	2200000
105.00	1	0	1	0	44200	63600	30000	0.0014145	2100000
110.00	1	0	1	0	44200	63600	30000	0.0014819	2000000
111.00	1	0	1	0	44200	63600	30000	0.0014954	2000000
113.00	1	0	1	0	44200	63600	30000	0.0015223	2000000
115.00	1	0	1	0	44200	63600	30000	0.0015493	1900000
126.00	1	0	1	0	44200	63600	30000	0.0016975	1800000
160.80	1	0	1	0	44200	63600	30000	0.0021663	1400000
162.00	1	0	1	0	44200	63600	30000	0.0021824	1400000
185.25	1	0	1	0	44200	63600	30000	0.0024957	1200000
188.00	1	0	1	0	44200	63600	30000	0.0025327	1200000
192.00	1	0	1	0	44200	63600	30000	0.0025866	1200000
194.00	1	0	1	0	44200	63600	30000	0.0026135	1100000
195.00	1	0	1	0	44200	63600	30000	0.0026270	1100000
200.00	1	0	1	0	44200	63600	30000	0.0026944	1100000
201.60	1	0	1	0	44200	63600	30000	0.0027159	1100000
264.00	1	0	1	0	44200	63600	30000	0.0035566	840000
291.60	1	0	1	0	44200	63600	30000	0.0039284	760000
312.00	1	0	1	0	44200	63600	30000	0.0042032	710000
312.00	1	0	1	0	44200	63600	30000	0.0042032	710000
324.00	1	0	1	0	44200	63600	30000	0.0043649	690000

TABLE E-8. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
388.80	1	0	1	0	44200	63600	30000	0.0052378	5700000
390.00	1	0	1	0	44200	63600	30000	0.0052540	5700000
395.00	1	16000	1	0	44200	63600	33700	0.0053214	6300000
432.00	1	0	1	0	44200	63600	30000	0.0058198	5200000
456.00	1	0	1	0	44200	63600	30000	0.0061432	4900000
504.00	1	0	1	0	44200	63600	30000	0.0067898	4400000
520.00	1	0	1	0	44200	63600	30000	0.0070054	4300000
557.30	1	0	1	0	44200	63600	30000	0.0075079	4000000
562.00	1	0	1	0	44200	63600	30000	0.0075712	4000000
581.00	1	0	1	0	44200	63600	30000	0.0078271	3800000
686.00	1	0	1	0	44200	63600	30000	0.0092417	3200000
804.00	1	0	1	0	44200	63600	30000	0.0108314	2800000
850.00	1	0	1	0	44200	63600	30000	0.0114511	2600000
875.00	1	0	1	0	44200	63600	30000	0.0117879	2500000
1092.00	1	0	1	0	44200	63600	30000	0.0147112	2000000
1155.00	1	16000	1	0	44200	63600	33700	0.0155600	2200000
1231.00	1	0	1	0	44200	63600	30000	0.0165838	1800000
1300.00	1	0	1	0	44200	63600	30000	0.0175134	1700000
1334.00	1	0	1	0	44200	63600	30000	0.0179714	1700000
1521.00	1	0	1	0	44200	63600	30000	0.0204907	1500000
1600.00	1	0	1	0	44200	63600	30000	0.0215549	1400000
1714.00	1	0	1	0	44200	63600	30000	0.0230907	1300000
1714.00	1	0	1	0	44200	63600	30000	0.0230907	1300000
1750.00	1	0	1	0	44200	63600	30000	0.0235757	1300000
1750.00	1	0	1	0	44200	63600	30000	0.0235757	1300000
1800.00	1	0	1	0	44200	63600	30000	0.0242493	1200000
1944.00	1	0	1	0	44200	63600	30000	0.0261892	1100000
1965.00	1	0	1	0	44200	63600	30000	0.0264721	1100000
1980.00	1	0	1	0	44200	63600	30000	0.0266742	1100000
2016.00	1	0	1	0	44200	63600	30000	0.0271592	1100000
2142.00	1	0	1	0	44200	63600	30000	0.0288567	1000000
2254.00	1	0	1	0	44200	63600	30000	0.0303655	1000000
2280.00	1	0	1	0	44200	63600	30000	0.0307158	1000000
2376.00	1	0	1	0	44200	63600	30000	0.0320091	940000
2419.20	1	0	1	0	44200	63600	30000	0.0325911	920000
2450.00	1	0	1	0	44200	63600	30000	0.0330060	910000
2527.00	1	0	1	0	44200	63600	30000	0.0340433	880000
2599.20	1	0	1	0	44200	63600	30000	0.0350160	860000
3120.00	1	0	1	0	44200	63600	30000	0.0420321	710000
3135.00	1	0	1	0	44200	63600	30000	0.0422342	710000
3240.00	1	0	1	0	44200	63600	30000	0.0436487	690000
3640.00	1	0	1	0	44200	63600	30000	0.0490375	610000
3755.00	1	0	1	0	44200	63600	30000	0.0505867	590000
4200.00	1	0	1	0	44200	63600	30000	0.0565817	530000

TABLE E-8. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
4200.00	1	0	1	0	44200	63600	30000	0.0565817	530000
4286.90	1	0	1	0	44200	63600	30000	0.0577524	520000
4320.00	1	0	1	0	44200	63600	30000	0.0581983	520000
4368.00	1	0	1	0	44200	63600	30000	0.0588450	510000
4667.00	1	0	1	0	44200	63600	30000	0.0628730	480000
4860.00	1	0	1	0	44200	63600	30000	0.0654731	460000
5016.00	1	16000	1	0	44200	82000	33700	0.0675747	500000
5088.00	1	0	1	0	44200	63600	30000	0.0685447	440000
5189.00	1	16000	1	0	44200	82000	33700	0.0699053	480000
5250.00	1	16000	1	0	44200	82000	33700	0.0707271	480000
5258.00	1	16000	1	0	44200	82000	33700	0.0708349	480000
5739.00	1	16000	1	0	44200	82000	33700	0.0773148	440000
5850.00	1	16000	1	0	44200	82000	33700	0.0788102	430000
6000.00	1	16000	1	0	44200	82000	33700	0.0808310	420000
6048.00	1	16000	1	0	44200	82000	33700	0.0814776	410000
6176.00	1	16000	1	0	44200	82000	33700	0.0832020	410000
6451.00	1	16000	1	0	44200	82000	33700	0.0869068	390000
6840.00	1	16000	1	0	44200	82000	33700	0.0921473	370000
6900.00	1	16000	1	0	44200	82000	33700	0.0929556	360000
7194.00	1	16000	1	0	44200	82000	33700	0.0969164	350000
7350.00	1	16000	1	0	44200	82000	33700	0.0990180	340000
7387.00	1	16000	1	0	44200	82000	33700	0.0995164	340000
8390.00	1	16000	1	0	44200	82000	33700	0.1130287	300000
8400.00	1	16000	1	0	44200	82000	33700	0.1131634	300000
8736.00	1	16000	1	0	44200	82000	33700	0.1176899	290000
9676.00	1	16000	1	0	44200	82000	33700	0.1303534	260000
10002.00	1	0	1	0	44200	63600	33700	0.1347453	250000
10613.00	1	16000	1	0	44200	82000	33700	0.1429765	240000
10800.00	1	16000	1	0	44200	82000	33700	0.1454958	230000
11016.00	1	16000	1	0	44200	82000	33700	0.1484057	230000
11400.00	2	32000	1	0	44200	121000	41700	0.1535789	270000
11440.00	2	32000	1	0	44200	121000	41700	0.1541178	270000
11547.00	2	32000	1	0	44200	121000	41700	0.1555592	270000
11984.00	2	32000	1	0	44200	121000	41700	0.1614464	260000
12020.00	2	32000	1	0	44200	121000	41700	0.1619314	260000
12249.00	2	32000	1	0	44200	121000	41700	0.1650165	250000
13000.00	2	32000	1	0	44200	121000	41700	0.1751338	240000
13000.00	2	32000	1	0	44200	121000	41700	0.1751338	240000
13059.00	2	32000	1	0	44200	121000	41700	0.1759286	240000
14352.00	2	32000	1	0	44200	121000	41700	0.1933477	220000
14400.00	2	32000	1	0	44200	121000	41700	0.1939944	210000
14860.00	3	48000	1	0	44200	143000	46100	0.2001914	230000
14862.00	3	48000	1	0	44200	143000	46100	0.2002184	230000

TABLE E-8. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
15040.00	2	32000	1	0	44200	121000	41700	0.2026163	210000
15600.00	1	16000	1	0	44200	82000	33700	0.2101606	160000
15724.00	2	32000	1	0	44200	121000	41700	0.2118311	200000
16426.00	1	0	1	0	44200	63600	30000	0.2212883	140000
16956.00	2	32000	1	0	44200	121000	41700	0.2284284	180000
18000.00	2	32000	1	0	44200	121000	41700	0.2424930	170000
18057.00	4	64000	1	0	44200	165000	50500	0.2432609	210000
18268.00	1	32000	1	0	44200	121000	41700	0.2461034	170000
18963.00	2	48000	1	0	44200	143000	46100	0.2554663	180000
19090.00	2	48000	1	0	44200	143000	46100	0.2571773	180000
21135.00	2	48000	1	0	44200	143000	46100	0.2847272	160000
22560.00	2	48000	1	0	44200	143000	46100	0.3039245	150000
23954.00	2	48000	1	0	44200	143000	46100	0.3227043	140000
24000.00	2	48000	1	0	44200	143000	46100	0.3233240	140000
24082.00	2	48000	1	0	44200	143000	46100	0.3244286	140000
26549.00	4	64000	1	0	44200	165000	50500	0.3576637	140000
29500.00	4	64000	1	0	44200	165000	50500	0.3974190	130000
29700.00	4	64000	1	0	44200	165000	50500	0.4001134	130000
30034.00	4	64000	1	0	44200	165000	50500	0.4046130	120000
30570.00	5	80000	0	1	74800	231000	75300	0.4118339	180000
32040.00	4	64000	1	0	44200	165000	50500	0.4316375	120000
34034.00	5	80000	0	1	74800	231000	75300	0.4585003	160000
35040.00	5	80000	0	1	74800	231000	75300	0.4720530	160000
36231.00	5	80000	0	1	74800	231000	75300	0.4880979	150000
38799.00	5	80000	0	1	74800	231000	75300	0.5226936	140000
39105.00	4	64000	1	0	44200	165000	50500	0.5268160	96000
40188.00	5	80000	0	1	74800	231000	75300	0.5414060	140000
41320.00	9	144000	0	1	74800	319000	93300	0.5566561	170000
43050.00	8	128000	0	1	74800	297000	88800	0.5799623	150000
45804.00	3	48000	1	0	44200	143000	46100	0.6170638	75000
50000.00	7	112000	0	1	74800	275000	84300	0.6735916	130000
52547.36	7	112000	0	1	74800	275000	84300	0.7079092	120000
52950.00	7	112000	0	1	74800	275000	84300	0.7133335	120000
54391.00	7	112000	0	1	74800	275000	84300	0.7327464	120000
55567.00	8	128000	0	1	74800	297000	88800	0.7485893	120000
56860.00	9	144000	0	1	74800	319000	93300	0.7660083	120000
64044.00	6	96000	0	1	74800	253000	79800	0.8627900	92000
66503.00	9	144000	0	1	74800	319000	93300	0.8959172	100000
78580.00	1	0	1	0	44200	63600	30000	1.0586165	28000
88000.00	11	176000	0	1	74800	363000	102000	1.1855212	86000
93450.00	11	176000	0	1	74800	363000	102000	1.2589427	81000
100524.00	13	208000	1	1	11900	470000	141000	1.3542424	100000
108408.00	18	288000	0	2	150000	626000	184000	1.4604543	130000
109897.00	6	96000	0	1	74800	253000	79800	1.4805139	54000

TABLE E-8. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	CAT_FOB	TCC	TAC	ARRED	CEFF
125084.00	9	144000	0	1	74800	319000	93300	1.6851106	55000
134956.00	19	304000	0	2	150000	648000	189000	1.8181045	100000
149000.00	10	160000	0	1	74800	340000	97500	2.0073029	49000
162287.00	10	160000	0	1	74800	340000	97500	2.1863031	45000
184511.60	11	176000	0	1	74800	363000	102000	2.4857092	41000
184766.00	11	176000	0	1	74800	363000	102000	2.4891364	41000
197260.00	22	352000	0	2	150000	713000	201000	2.6574535	76000
215000.00	15	240000	1	1	119000	514000	150000	2.8964438	52000
240030.00	16	256000	1	1	119000	537000	155000	3.2336437	48000
283998.00	17	272000	0	2	150000	603000	179000	3.8259732	47000

Notes for Table E-8

1. The field "AROOM" indicates facilities used in the model with an "*".
2. The field "EO_TOT" is the annual EP use at the facility.
3. The field "NUM CELLS" is the number of aeration cells assigned to that facility.
4. The field "COST CELLS" gives the cost of aeration cells.
5. The field "NUM_1000" is the number of 1,000 ft³/min control units.
6. The field "NUM_3000" is the number of 3,000 ft³/min control units.
7. The field "SAFE FOB" is the capital cost (FOB) of a gas/solid reactor control.
8. The field "TCC" gives the total capital cost for the facility.
9. The field "TAC" is the total annual control cost for the facility.
10. The field "ARRED" is the annual emission reduction (mg).
11. The field "CEFF" gives the cost effectiveness (\$/Mg).

TABLE E-9. AERATION ROOM CATALYTIC OXIDATION CONTROL COST ANALYSIS

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
1.50	1	0	1	0	17100	27500	9300	0.0000202	460000000
2.00	1	0	1	0	17100	27500	9300	0.0000269	350000000
2.98	1	0	1	0	17100	27500	9300	0.0000401	230000000
4.80	1	0	1	0	17100	27500	9300	0.0000647	140000000
6.00	1	0	1	0	17100	27500	9300	0.0000808	120000000
6.00	1	0	1	0	17100	27500	9300	0.0000808	120000000
6.00	1	0	1	0	17100	27500	9300	0.0000808	120000000
6.00	1	0	1	0	17100	27500	9300	0.0000808	120000000
7.50	1	0	1	0	17100	27500	9300	0.0001010	92000000
9.00	1	0	1	0	17100	27500	9300	0.0001212	77000000
12.00	1	0	1	0	17100	27500	9300	0.0001617	58000000
16.80	1	0	1	0	17100	27500	9300	0.0002263	41000000
17.80	1	0	1	0	17100	27500	9300	0.0002398	39000000
27.36	1	0	1	0	17100	27500	9300	0.0003686	25000000
32.40	1	0	1	0	17100	27500	9300	0.0004365	21000000
32.40	1	0	1	0	17100	27500	9300	0.0004365	21000000
32.40	1	0	1	0	17100	27500	9300	0.0004365	21000000
61.34	1	0	1	0	17100	27500	9300	0.0008264	11000000
64.00	1	0	1	0	17100	27500	9300	0.0008622	11000000
64.80	1	0	1	0	17100	27500	9300	0.0008730	11000000
65.00	1	0	1	0	17100	27500	9300	0.0008757	11000000
70.00	1	0	1	0	17100	27500	9300	0.0009430	9900000
93.60	1	0	1	0	17100	27500	9300	0.0012610	7400000
100.80	1	0	1	0	17100	27500	9300	0.0013580	6800000
105.00	1	0	1	0	17100	27500	9300	0.0014145	6600000
110.00	1	0	1	0	17100	27500	9300	0.0014819	6300000
111.00	1	0	1	0	17100	27500	9300	0.0014954	6200000
113.00	1	0	1	0	17100	27500	9300	0.0015223	6100000
115.00	1	0	1	0	17100	27500	9300	0.0015493	6000000
126.00	1	0	1	0	17100	27500	9300	0.0016975	5500000
160.80	1	0	1	0	17100	27500	9300	0.0021663	4300000
162.00	1	0	1	0	17100	27500	9300	0.0021824	4300000
185.25	1	0	1	0	17100	27500	9300	0.0024957	3700000
188.00	1	0	1	0	17100	27500	9300	0.0025327	3700000
192.00	1	0	1	0	17100	27500	9300	0.0025866	3600000
194.00	1	0	1	0	17100	27500	9300	0.0026135	3600000
195.00	1	0	1	0	17100	27500	9300	0.0026270	3500000
200.00	1	0	1	0	17100	27500	9300	0.0026944	3500000
201.60	1	0	1	0	17100	27500	9300	0.0027159	3400000
264.00	1	0	1	0	17100	27500	9300	0.0035566	2600000
291.60	1	0	1	0	17100	27500	9300	0.0039284	2400000
312.00	1	0	1	0	17100	27500	9300	0.0042032	2200000
312.00	1	0	1	0	17100	27500	9300	0.0042032	2200000
324.00	1	0	1	0	17100	27500	9300	0.0043649	2100000

TABLE E-9. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
388.80	1	0	1	0	17100	27500	9300	0.0052378	1800000
390.00	1	0	1	0	17100	27500	9300	0.0052540	1800000
395.00	1	16000	1	0	17100	45900	13000	0.0053214	2400000
432.00	1	0	1	0	17100	27500	9300	0.0058198	1600000
456.00	1	0	1	0	17100	27500	9300	0.0061432	1500000
504.00	1	0	1	0	17100	27500	9300	0.0067898	1400000
520.00	1	0	1	0	17100	27500	9300	0.0070054	1300000
557.30	1	0	1	0	17100	27500	9300	0.0075079	1200000
562.00	1	0	1	0	17100	27500	9300	0.0075712	1200000
581.00	1	0	1	0	17100	27500	9300	0.0078271	1200000
686.00	1	0	1	0	17100	27500	9300	0.0092417	1000000
804.00	1	0	1	0	17100	27500	9300	0.0108314	860000
850.00	1	0	1	0	17100	27500	9300	0.0114511	810000
875.00	1	0	1	0	17100	27500	9300	0.0117879	790000
1092.00	1	0	1	0	17100	27500	9300	0.0147112	630000
1155.00	1	0	1	0	17100	27500	9300	0.0155600	600000
1231.00	1	0	1	0	17100	27500	9300	0.0165838	560000
1300.00	1	0	1	0	17100	27500	9300	0.0175134	530000
1334.00	1	0	1	0	17100	27500	9300	0.0179714	520000
1521.00	1	0	1	0	17100	27500	9300	0.0204907	450000
1600.00	1	0	1	0	17100	27500	9300	0.0215549	430000
1714.00	1	0	1	0	17100	27500	9300	0.0230907	400000
1714.00	1	0	1	0	17100	27500	9300	0.0230907	400000
1750.00	1	0	1	0	17100	27500	9300	0.0235757	390000
1750.00	1	0	1	0	17100	27500	9300	0.0235757	390000
1800.00	1	0	1	0	17100	27500	9300	0.0242493	380000
1944.00	1	0	1	0	17100	27500	9300	0.0261892	360000
1965.00	1	0	1	0	17100	27500	9300	0.0264721	350000
1980.00	1	0	1	0	17100	27500	9300	0.0266742	350000
2016.00	1	0	1	0	17100	27500	9300	0.0271592	340000
2142.00	1	0	1	0	17100	27500	9300	0.0288567	320000
2254.00	1	0	1	0	17100	27500	9300	0.0303655	310000
2280.00	1	0	1	0	17100	27500	9300	0.0307158	300000
2376.00	1	0	1	0	17100	27500	9300	0.0320091	290000
2419.20	1	0	1	0	17100	27500	9300	0.0325911	290000
2450.00	1	0	1	0	17100	27500	9300	0.0330060	280000
2527.00	1	0	1	0	17100	27500	9300	0.0340433	270000
2599.20	1	0	1	0	17100	27500	9300	0.0350160	270000
3120.00	1	0	1	0	17100	27500	9300	0.0420321	220000
3135.00	1	0	1	0	17100	27500	9300	0.0422342	220000
3240.00	1	0	1	0	17100	27500	9300	0.0436487	210000
3640.00	1	0	1	0	17100	27500	9300	0.0490375	190000
3755.00	1	0	1	0	17100	27500	9300	0.0505867	180000
4200.00	1	0	1	0	17100	27500	9300	0.0565817	160000

TABLE E-9. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
4200.00	1	0	1	0	17100	27500	9300	0.0565817	160000
4286.90	1	0	1	0	17100	27500	9300	0.0577524	160000
4320.00	1	0	1	0	17100	27500	9300	0.0581983	160000
4368.00	1	0	1	0	17100	27500	9300	0.0588450	160000
4667.00	1	0	1	0	17100	27500	9300	0.0628730	150000
4860.00	1	0	1	0	17100	27500	9300	0.0654731	140000
5016.00	1	16000	1	0	17100	45900	13000	0.0675747	190000
5088.00	1	0	1	0	17100	27600	9300	0.0685447	140000
5189.00	1	16000	1	0	17100	45900	13000	0.0699053	190000
5250.00	1	16000	1	0	17100	45900	13000	0.0707271	180000
5258.00	1	16000	1	0	17100	45900	13000	0.0708349	180000
5739.00	1	16000	1	0	17100	45900	13000	0.0773148	170000
5850.00	1	16000	1	0	17100	45900	13000	0.0788102	160000
6000.00	1	16000	1	0	17100	45900	13000	0.0808310	160000
6048.00	1	16000	1	0	17100	45900	13000	0.0814776	160000
6176.00	1	16000	1	0	17100	45900	13000	0.0832020	160000
6451.00	1	16000	1	0	17100	45900	13000	0.0869068	150000
6840.00	1	16000	1	0	17100	45900	13000	0.0921473	140000
6900.00	1	16000	1	0	17100	45900	13000	0.0929556	140000
7194.00	1	16000	1	0	17100	45900	13000	0.0969164	130000
7350.00	1	16000	1	0	17100	45900	13000	0.0990180	130000
7387.00	1	16000	1	0	17100	45900	13000	0.0995164	130000
8390.00	1	16000	1	0	17100	45900	13000	0.1130287	120000
8400.00	1	16000	1	0	17100	45900	13000	0.1131634	110000
8736.00	1	16000	1	0	17100	45900	13000	0.1176899	110000
9676.00	1	16000	1	0	17100	45900	13000	0.1303534	100000
10002.00	1	0	1	0	17100	27500	9300	0.1347453	69000
10613.00	1	16000	1	0	17100	45900	13000	0.1429765	91000
10800.00	1	16000	1	0	17100	45900	13000	0.1454958	89000
11016.00	1	16000	1	0	17100	45900	13000	0.1484057	88000
11400.00	2	32000	1	0	17100	74600	18800	0.1535789	120000
11440.00	2	32000	1	0	17100	74600	18800	0.1541178	120000
11547.00	2	32000	1	0	17100	74600	18800	0.1555592	120000
11984.00	2	32000	1	0	17100	74600	18800	0.1614464	120000
12020.00	2	32000	1	0	17100	74600	18800	0.1619314	120000
12249.00	2	32000	1	0	17100	74600	18800	0.1650165	110000
13000.00	2	32000	1	0	17100	74600	18800	0.1751338	110000
13000.00	2	32000	1	0	17100	74600	18800	0.1751338	110000
13059.00	2	32000	1	0	17100	74600	18800	0.1759286	110000
14352.00	2	32000	1	0	17100	74600	18800	0.1933477	97000
14400.00	2	32000	1	0	17100	74600	18800	0.1939944	97000
14860.00	3	48000	1	0	17100	94800	22900	0.2001914	110000
14862.00	3	48000	1	0	17100	94800	22900	0.2002184	110000
15040.00	2	32000	1	0	17100	74600	18800	0.2026163	93000

TABLE E-9. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
15600.00	1	16000	1	0	17100	45900	13000	0.2101606	62000
15724.00	2	32000	1	0	17100	74600	18800	0.2118311	89000
16426.00	1	0	1	0	17100	27500	9300	0.2212883	42000
16956.00	2	32000	1	0	17100	74600	18800	0.2284284	82000
18000.00	2	32000	1	0	17100	74600	18800	0.2424930	78000
18057.00	4	64000	1	0	17100	115000	27000	0.2432609	110000
18268.00	1	32000	1	0	17100	74600	18800	0.2461034	76000
18963.00	2	48000	1	0	17100	94800	22900	0.2554663	90000
19090.00	2	48000	1	0	17100	94800	22900	0.2571773	89000
21135.00	2	48000	1	0	17100	94800	22900	0.2847272	80000
22560.00	2	48000	1	0	17100	94800	22900	0.3039245	75000
23954.00	2	48000	1	0	17100	94800	22900	0.3227043	71000
24000.00	2	48000	1	0	17100	94800	22900	0.3233240	71000
24082.00	2	48000	1	0	17100	94800	22900	0.3244286	71000
26549.00	4	64000	1	0	17100	115000	27000	0.3576637	75000
29500.00	4	64000	1	0	17100	115000	27300	0.3974190	69000
29700.00	4	64000	1	0	17100	115000	27300	0.4001134	68000
30034.00	4	64000	1	0	17100	115000	27300	0.4046130	67000
30570.00	5	80000	0	1	37000	167000	46400	0.4118339	110000
32040.00	4	64000	1	0	17100	115000	27400	0.4316375	63000
34034.00	5	80000	0	1	37000	167000	46400	0.4585003	100000
35040.00	5	80000	0	1	37000	167000	46400	0.4720530	98000
36231.00	5	80000	0	1	37000	167000	46400	0.4880979	95000
38799.00	5	80000	0	1	37000	167000	46400	0.5226936	89000
39105.00	4	64000	1	0	17100	115000	28000	0.5268160	53000
40188.00	5	80000	0	1	37000	167000	46400	0.5414060	86000
41320.00	9	144000	0	1	37000	248000	62900	0.5566561	110000
43050.00	8	128000	0	1	37000	228000	58900	0.5799623	100000
45804.00	3	48000	1	0	17100	94800	24300	0.6170638	39000
50000.00	7	112000	0	1	37000	208000	54800	0.6735916	81000
52547.36	7	112000	0	1	37000	208000	54800	0.7079092	77000
52950.00	7	112000	0	1	37000	208000	54800	0.7133335	77000
54391.00	7	112000	0	1	37000	208000	54800	0.7327464	75000
55567.00	8	128000	0	1	37000	208000	58900	0.7485893	79000
56860.00	9	144000	0	1	37000	248000	32900	0.7660083	43000
64044.00	6	96000	0	1	37000	188000	50800	0.8627900	59000
66503.00	9	144000	0	1	37000	248000	62900	0.8959172	70000
78580.00	1	0	1	0	17100	27500	13200	1.0586165	12000
88000.00	11	176000	0	1	37000	289000	71900	1.1855212	61000
93450.00	11	176000	0	1	37000	289000	72300	1.2589427	57000
100524.00	13	208000	1	1	54100	357000	88600	1.3542424	65000
108408.00	18	288000	0	2	73900	489000	124000	1.4604543	85000
109897.00	6	96000	0	1	37000	188000	52900	1.4805139	36000
125084.00	9	144000	0	1	37000	248000	66300	1.6851106	39000

TABLE E-9. (continued)

EO_TOT	NUM_CELLS	COST_CELLS	NUM_1000	NUM_3000	SAFE_FOB	TCC	TAC	ARRED	CEFF
134956.00	19	304000	0	2	73900	510000	129000	1.8181045	71000
149000.00	10	160000	0	1	37000	268000	72100	2.0073029	36000
162287.00	10	160000	0	1	37000	268000	73100	2.1863031	33000
184511.60	11	176000	0	1	37000	289000	79100	2.4857092	32000
184766.00	11	176000	0	1	37000	289000	79100	2.4891364	32000
197260.00	22	352000	0	2	73900	570000	144000	2.6574535	54000
215000.00	15	240000	1	1	54100	397000	105000	2.8964438	36000
240030.00	16	256000	1	1	54100	418000	111000	3.2336437	34000
283998.00	17	272000	0	2	73900	469000	130000	3.8259732	34000

E.3 AERATION ROOM COST ANALYSIS

Notes for Table E-9

1. The field "AROOM" indicates facilities used in the model with an "*".
2. The field "EO_TOT" is the annual EO use at the facility.
3. The field "NUM_CELLS" is the number of aeration cells assigned to that facility.
4. The field "COST_CELLS" gives the cost of aeration cells.
5. The field "NUM_1000" is the number of 1,000 ft³/min control units.
6. The field "NUM_3000" is the number of 3,000 ft³/min control units.
7. The field "CAT_FOB" is the capital cost (FOB) of a catalytic oxidation control.
8. The field "TCC" gives the total capital cost for the facility.
9. The field "TAC" is the total annual control cost for the facility.
10. The field "ARRED" is the annual emission reduction (mg).
11. The field "CEFF" gives the cost effectiveness (\$/Mg).

REFERENCES

1. Letter and attachments from Olson, C., Donaldson Company, Inc., to S. Srebro. MRI. March 23, 1989. Capital and operating costs of 1,000 ft³/min EtO Abator™ catalytic oxidizer.
2. Telecon. Srebro, S., MRI, with C. Olson. Donaldson Company, Inc. April 4, 1989. Discussion about costs of EtO Abator™.
3. Telecon. Nicholson, R., MRI, with C. Olson. Donaldson, Company, Inc. May 12 and June 13, 1988. Costs of EtO Abators™.
4. Chemical Engineering. Economic Indicators. April 25, 1988. p. 9.

5. Chemical Engineering. Economic Indicators. June 1989.
p. 224.

E.4 EXAMPLE FACILITY CALCULATIONS

TABLE E-10. CAPITAL AND ANNUAL COSTS OF INSTALLING SCRUBBERS¹
(4th Quarter 1987 Dollars)

Item	Cost
A. CAPITAL COSTS^a	
1. <u>Installed equipment costs</u>	
a. Acid/water scrubber ^b	98,900
b. Explosion-proof valves for scrubber ^c	N/A ^c
c. Chlorine filter house ^d	166
d. Purchased equipment costs, total	99,100
e. Installation of scrubber ^e	49,500
f. Installation of chlorine filters	80
g. Taxes: 5 percent of equipment cost	4,960
h. Freight: 5 percent of equipment cost	4,960
i. Vacuum pump ^f	0
j. Manifolding of chambers (includes check valve) ^g	463
k. Subtotal Capital Costs	159,000
l. Contingencies ^h	15,900
TOTAL CAPITAL INVESTMENT	175,000
B. ANNUAL COSTS^a	
1. <u>Direct operating costs</u>	
a. Labor ⁱ	3,540
b. Materials	
50 percent H ₂ SO ₄ ^j	364
50 percent NaOH ^k	350
Chlorine filters ^l	
Taxes: 5 percent of materials cost	117
Freight: 5 percent of materials cost	42
c. Water ^m	42
d. Electricity ⁿ	0
e. Compressed air ^o	124
f. Disposal of ethylene glycol ^p	0
	4,040
2. <u>Indirect operating costs</u>	
a. Overhead: 0.60 x labor ⁴⁰	
b. Property tax, insurance, and administration ^q	2,120
c. Capital recovery costs ^r	7,000
	28,500
TOTAL ANNUAL COSTS	46,200
C. COST EFFECTIVENESS	
1. Emission reduction, Mg EO/yr (tons EO/yr)	6.8 (7.5)
2. Cost effectiveness, 1987, \$/Mg (\$/ton EO)	6,800 (6,200)

TABLE E-10. (continued)

- ^aCosts rounded to three significant figures.
- ^bModel 400 based on largest chamber size of 1,000 ft³.
- ^cNot applicable.
- ^dOne per tank at \$41.50 each (four tanks--Model 400).
- ^eFifty percent of scrubber cost.
- ^fOne at \$5,170. The cost of the first vacuum pump is included in the installation cost of the scrubber.
- ^gSee Table E-4. One chamber costed for a check valve at \$463.
- ^hAssumed to be 10 percent of subtotal capital costs to account for uncertainties in the capital cost estimates.
- ⁱLabor was calculated for 0.25 person-hours/shift, 3 shifts/day, 365 days/year for system inspection and 16 person-hours for each regeneration of the scrubber at \$11.65/person-hour.
- ^jThe cost of acid is calculated, $(\text{UNC_FAC}) \div (2,000) \times (594) \times (\$0.070) \times 1.15$. (15 percent extra is for spillage.) (UNC_FAC) is equal to uncontrolled emissions (lb) from vent and drain at baseline.)
- ^kThe cost of caustic is calculated, $\text{No. drum} = (\text{UNC_FAC}) \div (2,000) \times (250) \div (350)$. $\text{No. drum} = 5.4$; therefore, unit cost = \$0.0802. Total cost = $(\text{No. drums}) \times (700) \times (0.0802) \times 1.15$ (15 percent extra for spillage).
- ^lChlorine filter cost is $(\text{UNC_FAC}) \times (15) \div (2,000)$.
- ^mCalculated as $(\text{scrubber model}) \times (2) \times (\text{UNC_FAC}) / [(2,000) \times (\text{No. of tanks})] \times (0.25/1,000)$.
- ⁿSee preceeding notes for calculation methodology.
- ^oThe cost of 10 seconds of house-supplied compressed air per cycle was considered negligible.
- ^pDisposal cost is $(\text{UNC_FAC}) \div (2,000) \times (4,845) \times (0.110)$.
- ^qCalculated as 4 percent of total capital costs.
- ^rCalculated as $(0.16275) \times (\text{total capital costs})$ for an interest rate of 10 percent and a 10-year recovery period.

TABLE E-11. CAPITAL AND ANNUAL COSTS OF INSTALLING SCRUBBERS
TO CONTROL CHAMBER EXHAUST VENTS²
(4th Quarter 1987 Dollars)

Item	Cost
A. CAPITAL COSTS^a	
1. <u>Installed equipment costs</u>	
a. Acid/water scrubber ^b	44,900
b. Chlorine filter house ^c	42
c. Purchased equipment costs, total ^d	44,900
d. Installation of chlorine filters ^d	20
e. Sales tax: 5 percent of equipment cost ^d	2,240
f. Freight: 5 percent of equipment cost ^d	2,240
g. Manifolding of vents ^e	8,410
TOTAL CAPITAL INVESTMENT ^f	117,000
B. ANNUAL COSTS^a	
1. <u>Direct operating costs</u>	
a. Labor ^g	3,310
b. Materials	
(1) 50 percent H ₂ SO ₄ ^h	31
(2) 50 percent NaOH ⁱ	42
(3) Chlorine filters ^j	10
(4) Taxes: 5 percent of materials cost	4
(5) Freight: 5 percent of materials cost	4
c. Water ^k	0
d. Electricity ^l	82
e. Compressed air ^m	0
f. Disposal of ethylene glycol ⁿ	350
2. <u>Indirect operating costs</u>	
a. Overhead: 0.60 x labor	1,990
b. Property tax, insurance, and administration ^o	4,680
c. Capital recovery costs ^p	19,000
TOTAL ANNUAL COSTS	29,500
C. COST EFFECTIVENESS^a	
1. Emission reduction, Mg EO/yr (ton EO/yr)	0.71 (0.78)
2. Cost effectiveness, 1987, \$/Mg EO (\$/ton EO)	30,000 (27,000)

TABLE E-11. (continued)

^aCapital and annual costs rounded to three significant figures. Cost effectiveness rounded to two significant figures.

^bFacility has four chambers. Therefore, costed for a 6,000 ft³/min scrubber.

^cOne per tank at \$41.50 each.

^dCapital equipment cost.

^eSee Section E.5 for a detailed summary of manifolding costs.

^fCapital costs were increased by a factor of 2.2 (except manifolding costs) to account for additional capital expenditures necessary to install the control. The total capital costs were calculated as $(2.2 \times [\text{sum of items with superscript d}]) + \text{manifolding costs}$.

^gLabor was calculated for 0.25 person-hours/shift, 3 shifts/day, 365 days/year for system inspection and 16 person-hours for each regeneration of the scrubber at \$11.65/person-hour.

^hThe cost of acid is calculated, $(\text{UNC_RCE}) \div (2,000) \times (594) \times (\$0.070) \times 1.15$. (Extra 15 percent for spillage.) (UNC_RCE is equal to uncontrolled emissions (lb) from rear chamber exhaust vents.)

ⁱThe cost of caustic is calculated, $\text{No. drum} = (\text{UNC-RCE}) \div (2,000) \times (250) \div (350)$. $\text{No. drum} = 0.6$; therefore, unit cost = \$0.110. Total cost = $(\text{No. drums}) \times (700) \times (\$0.11) \times 1.15$ (15 percent extra for spillage).

^jChlorine filter cost is $(\text{UNC_RCE}/2,000) \times 15$.

^kCalculated as $(\text{scrubber model}) \times (2) \times (\text{UNC_RCE}/2,000) \times (0.25/1,000)$.

^lSee preceeding notes for calculation methodology.

^mThe cost of 10 seconds of house-supplied compressed air per cycle was considered negligible.

ⁿDisposal cost is $(\text{UNC_RCE}) \div (2,000) \times (4,845) \times (0.110)$.

^oCalculated as 4 percent of total capital investment.

^pCalculated as $(0.16275) \times (\text{total capital investment})$ (i.e., an interest rate of 10 percent and a 10-year recovery period).

TABLE E-12. CAPITAL AND ANNUAL COSTS OF GAS/SOLID REACTOR
TO CONTROL AERATION UNITS AT AN EXAMPLE FACILITY³
(4TH QUARTER 1987 Dollars)

Item	Cost, \$
A. CAPITAL COSTS	
1. <u>Installed Equipment Costs</u>	
a. Gas/solid reactor	17,100
b. Installation of gas/solid reactor ^a	5,130
c. Taxes: 5 percent of equipment cost	855
d. Freight: 5 percent of equipment cost	855
e. Aeration units, installed cost ^b	32,000
f. Manifolding of aeration units ^c	9,830
g. Subtotal capital costs	65,800
h. Contingencies ^d	9,870
TOTAL CAPITAL COSTS	75,700
B. ANNUAL COSTS	
1. <u>Direct operating Costs</u>	
a. Maintenance labor ^e	151
b. Maintenance materials ^f	76
c. Reactant replacement ^g	2,480
d. Labor for reactant replacement ^h	70
e. Electricity ⁱ	416
f. Disposal of reactant ^j	812
2. <u>Indirect Operating Costs</u>	
a. Overhead ^k	136
b. Property tax, insurance, and administration ^l	3,030
c. Capital recovery costs ^m	11,900
TOTAL ANNUAL COSTS	19,100
C. COST EFFECTIVENESS	
1. Emission reduction, Mg EO/yr (ton EO/yr)	0.176 (0.194)
2. Cost effectiveness, \$/Mg EO (\$/ton EO)	110,000 (100,000)

TABLE E-12. (continued)

- ^aCalculated as 30 percent of gas/solid reactor cost.
- ^bIncludes ductwork. Each aeration unit cost \$16,000 installed. The example facility would require two aeration units.
- ^cSee Section E.5 for a detailed summary of manifolding costs.
- ^dAssumed to be 15 percent of the subtotal capital costs to account for uncertainties in the capital cost estimates.
- ^eAssumed 15 minutes per week (52 weeks per year) for a 1,000 ft³/min system and 20 minutes per week for a 3,000 ft³/min control system for system inspection and general maintenance. Labor rate (\$11.65 per hour) was calculated as (323.8/218.8) x (\$7.87 per hour).
- ^fMaintenance materials were calculated as (0.5) x (maintenance labor).
- ^gThe maximum reactant life is 1.5 years but could be shorter depending on the amount of EO being controlled (in pounds). Assumed that control requires 4 pounds of reactant per ft³/min of airflow and that each pound of reactant can control 0.3 lb of EO. If the pounds of EO through the control (in a 1 1/2-year period) exceed the maximum capacity of the unit, then the reactant life is calculated as follows: $[(0.3 \text{ lb EO/lb reactant}) \times (4 \text{ lb reactant/ft}^3/\text{min of flow}) \times (\text{flow rate, ft}^3/\text{min})] / \text{maximum capacity of the unit, in pounds of EO} \times 1.5$ years. Reactant replacement costs were calculated as (flow rate, ft³/min) x (4 lb reactant/ft³/min of flow rate) x (\$1/lb of reactant) x (340.8/412). Where 340.8/412 is the Chemical Engineering cost indice to convert from 1989 to 1987 dollars.^hEach 1,000 ft³/min control unit requires about 8 person hours to refill. Depending on the interval of reactant replacement, capital recovery factors were determined as $[CRC = i(i + 1)^n / (i + 1)^n - 1]$ where $i = 0.1$ (10 percent interest) and $n = \text{life (years)}$. Labor costs were calculated as (\$7.87 per hour) x (323.8/218.8) x (CRC).
- ⁱThe 1,000 and 3,000 ft³/min systems are equipped with 1.1 and 10 kW (1.5 and 13.5 horsepower) fans, respectively. Electricity costs were calculated based on 365 days per year at continuous (24 hour) operation and an electricity cost of \$0.0432 kWh. Costs were calculated as (365 days per year)(24 hours per day)(fan power)(\$0.0432 kWh).
- ^jDisposal costs were developed assuming the reactant would be recycled and that there would be no credit or charge for the reactant. Transportation costs were calculated assuming a distance of 1,500 miles at a charge of \$0.15 per pound for less than 5,000 pounds and \$0.12 per pound for a shipment greater than 5,000 pounds.
- ^kCalculated as 60 percent of the sum of the maintenance labor and maintenance materials.
- ^lCalculated as 4 percent of total capital costs.
- ^mAssumed life of 10 years for gas/solid reactor oxidizer and aeration unit and an interest rate of 10 percent. Assumed a life of 20 years and a 10 percent interest rate for manifolding materials. Capital recovery cost was calculated as $0.16275 / [(total \text{ capital costs}) - (cost \text{ to change catalyst} + labor \text{ to change catalyst} + manifolding costs)] + (0.1175) \times (\text{manifolding costs})$ where 0.16275 and 0.1175 are the capital recovery factors for the catalytic oxidizer and manifolding, respectively.

TABLE E-13. CAPITAL AND ANNUALIZED COSTS OF CATALYTIC OXIDATION
AT AN EXAMPLE FACILITY³
(4th Quarter 1987 Dollars)

Item	Cost, \$
A. CAPITAL COSTS	
1. <u>Installed Equipment Costs</u>	
a. Catalytic oxidizer(s)	47,800
b. Installation of catalytic oxidizer ^a	7,170
c. Taxes: 5 percent of equipment cost	2,390
d. Freight: 5 percent of equipment cost	2,390
e. Aeration units, installed cost ^b	32,000
f. Manifolding of aeration units ^c	19,700
g. Subtotal capital costs	111,000
h. Contingencies ^d	16,700
TOTAL CAPITAL COSTS	128,000
B. ANNUAL COSTS	
1. <u>Direct Operating Costs</u>	
a. Maintenance labor ^e	1,060
b. Maintenance materials ^f	150
c. Catalyst replacement ^g	1,460
d. Labor for catalyst replacement ^h	15
e. Electricity ⁱ	13,900
f. Disposal of catalyst ^j	21
2. <u>Indirect Operating Costs</u>	
a. Overhead ^k	726
b. Property tax, insurance, and administration ^l	5,120
c. Capital recovery costs ^m	20,600
TOTAL ANNUAL COSTS	43,100
C. COST EFFECTIVENESS	
1. Emission reduction, Mg EO/yr (ton EO/yr)(0.194)	0.176 (0.194)
2. Cost effectiveness, \$/Mg EO (\$/ton EO)	240,000 (220,000)

TABLE E-13. (continued)

- ^aCalculated as 15 percent of catalytic oxidation cost.
- ^bIncludes ductwork. Each aeration unit cost \$16,000 installed. The example facility would require two aeration units.
- ^cSee Section E.5 for a detailed summary of manifolding costs.
- ^dAssumed to be 15 percent of the subtotal capital costs to account for uncertainties in the capital cost estimates.
- ^eAssumed 15 minutes per day (365 days per year) for system inspection and general maintenance of a 1,000 ft³/min system and an additional 5 minutes for each step up in catalytic oxidizer size. Labor rate (\$11.65 per hour) was calculated as $(323.8/218.8) \times (\$7.87/h)$.
- ^fAssumed \$150 a year (base cost) for 1,000 ft³/min unit and an additional \$50 a year for each step up in catalytic oxidizer size.
- ^gThe 1,000, 3,000, 6,000, 9,000, and 12,000 ft³/min catalytic oxidizers have 4, 16, 32, 48, and 64 catalytic cells, respectively. Each cell costs approximately \$1,240 to refill. Costs were annualized over a 4-year life at 10 percent interest using a capital recovery factor of 0.31547.
- ^hEach cell requires about 1-person hour to refill. Refill labor costs were annualized over 4 years assuming a 10 percent interest rate using a capital recovery factor of 0.31547.
- ⁱThe 1,000, 3,000, 6,000, 9,000, and 12,000 ft³/min systems have 80, 120, 180, 230, and 290 kilowatt (kW) catalytic oxidizer preheaters, respectively. System designed for 70 percent heat recovery uses only 46 percent of rated kW. Electricity cost calculated as $(\$0.0432/kWh) \times (kW \text{ of heater}) \times (0.46) \times (24 \text{ hours per day}) \times (365 \text{ days per year})$. No costs were attributed to fan electrical consumption because the preheating electrical costs were considerably larger.
- ^jDisposal costs calculated as $[(\$80/400 \text{ lb}) \times (90 \text{ lb cell}) \times (\text{No. of cells})] / 4 \text{ years}$. Includes transportation to an industrial landfill calculated as \$25 per 55-gallon drum (7.35 ft³/drum). Density of catalyst is 1 g/cm³ (62.4 lb/ft³). Transportation equals $[(90 \text{ lb/cell}) \times (\$25/\text{drum}) \times (\text{No. of cells})] / [(62.4 \text{ lb/ft}^3) \times (7.35 \text{ ft}^3/\text{drum}) \times (4 \text{ yr})]$. All disposal costs were multiplied by (329.8/354.2) to correct to 1987 dollars.
- ^kCalculated as 60 percent of the sum of the maintenance labor and maintenance materials.
- ^lCalculated as 4 percent of total capital costs.
- ^mAssumed life of 10 years for catalytic oxidizer and aeration unit and an interest rate of 10 percent. Assumed a life of 20 years and a 10-percent interest rate for manifolding materials. Capital recovery cost was calculated as $0.16275 \times [(\text{total capital costs}) - (\text{cost to change catalyst} + \text{labor to change catalyst} + \text{manifolding costs})] + (0.1175) \times (\text{manifolding costs})$ where 0.16275 and 0.1175 are the capital recovery factors for the catalytic oxidizer and manifolding, respectively.

E.4 EXAMPLE FACILITY CALCULATIONS

REFERENCES

1. Memorandum. Srebro, S., to D. Markwordt. EPA/CPB. Cost Effectiveness of Reducing Ethylene Oxide Emissions from Sterilizer Vents and Associated Vacuum Pump Drains. March 21, 1991.
2. Memorandum. deOlloqui, V., and Srebro, S., to D. Markwordt. EPA/CPB. Costing of Control Alternatives for the Rear Chamber Exhaust Emissions. March 21, 1991.
3. Memorandum. Srebro, S., and deOlloqui, V., to D. Markwordt. EPA/CPB. Costing Methodology for the Control of Aeration Room Emissions. March 21, 1991.

E.5 MANIFOLDING COSTS

TABLE E-14. INCREMENTAL CAPITAL COSTS OF MANIFOLDING
STERILIZATION CHAMBERS, 1987, \$

	Cost 1987, \$	Reference ¹
1. <u>Opening in explosion-proof wall</u>		
Cost	2 ^a c	3-100, p. 12
Adjustable sheet metal sleeve		
Labor hours		
Concrete core drilling, 1-in. to 3-in. hole	4.4	3-100, p. 22
Adjustable sheet metal sleeve	0.75	3-100, p. 22
Total labor hours	5.15	
Labor costs at \$18.91/labor hour	97 ^a	3-0, p. 2
Overhead costs at \$8.75/labor hour	45 ^b	1-0, p. 5
2. <u>Drill hole for pipe hangers</u>		
Labor hours		
3/8 in. diameter hole through 1/2 in. thick steel beam, 20 holes	7.5	5-10, p. 16
Labor costs at \$20.32/person-hour	153 ^a	5-0, p. 1
Overhead costs at \$15.78/person-hour	118 ^b	1-0, p. 5
3. <u>Piping</u>		
Cost		
100 ft, 2 in. diameter, 40 standard carbon steel pipe	251 ^a c	15-43, p. 4
90° elbows, 3 at \$4.40	14 ^a c	15-43, p.9
Tee with full-size outlet	15 ^a c	15-43, p. 13
Swing check valve	367 ^a c	15-43, p. 31
Bolts and gaskets, two sets at \$7.08	15 ^a c	15-72, p. 3
Pipe hangers, 1 carton of 50 hangers	147 ^a c	15-76, p. 25
Total cost	808	
Labor hours to install		
Cut, three at 0.16 labor hours	0.48	15-77, p. 27
Bevel, three at 0.10 labor hours	0.30	15-77, p. 30
Pipe	8.3	15-43, p. 4
Field erection joint buttweld	2.9	15-43, p. 29
Penetration through one wall	1.7	15-43, p. 8
Elbows, three at 2.00 labor hours	6.0	15-43, p. 9
Tee	3.0	
Valve	1.1	15-43, p. 13
Boltup of valve, two sets at 1.35 labor hours	2.7	15-43, p. 31
Pipe hangers, 10 at 0.16 labor hours	1.6	15-72, p. 3
Total labor hours	28.0	15-76, p. 35
Labor costs at \$21.47/labor hour	601 ^a	15-0, p. 2
Overhead costs at \$13.31/labor hour	373 ^b	1-0, p. 5
4. <u>Total installed cost for piping system</u>		
Total direct costs	1,663 ^d	
Total overhead costs	536 ^e	
Administration	152 ^f	1-0, p. 6
10 percent of total direct costs		
Taxes: 5 percent of equipment costs	33 ^g	1-0, p. 6
Total indirect costs	721 ^h	
Total installed cost	2,384 ⁱ	

TABLE E-14. (continued)

	Cost 1987, \$	Reference ¹
5. <u>Total installed cost for new vacuum pump</u>	5,170 ^j	MRI report ²
6. <u>Total installed capital cost</u>	7,554 ^k	

^aDirect cost.

^bOverhead cost.

^cEquipment cost.

^dTotal of costs with superscript a.

^eTotal of costs with superscript b.

^fAdministration = $0.10 \times (\text{sum of costs with superscript a})$

^gTaxes = $0.05 \times \text{sum of costs with superscript c.}$

^hTotal indirect costs = sum of costs with superscripts e, f, and g.

ⁱTotal installed cost = total direct costs (superscript d) + total indirect costs (superscript h).

^j\$5,000 (1986 \$) $\times 1.034$ (see Section E.2).

^kEqual to total installed cost for piping (superscript i) + total installed cost for new vacuum pump (superscript j).

TABLE E-15. DUCTWORK COSTS OF MANIFOLDING CHAMBER EXHAUST VENTS TO A SCRUBBER

Item	Cost, \$, 1987	Reference ^{1,3}
<u>Chamber exhaust vent to manifold^a</u>		
1. 15 ft 10-in. diameter, 1/8 in. thick carbon steel	210	Gard, p. 4-19
2. 90° elbow, 10-in. diameter	204	Gard, p. 4-22
3. Labor ^b	164	Richardson, 15-9 p. 2
<u>Manifold</u>		
1. 36 ft 41-in. diameter, 1/8 in. thick carbon steel	2,290	Gard, p. 4-19
2. Labor ^b	1,352	Richardson, 15-9 p. 2
<u>Manifold to control unit</u>		
1. 30 ft 24-in. diameter, 1.8 in. thick carbon steel	1,110	Gard, p. 4-19
2. 90° elbow, 24-in. diameter		
3. Tec, 24-in. diameter	580	Gard, p. 4-22
4. Labor ^b	192	Gard, p. 4-22
	769	Richardson, 15-9 p. 2

^aCosts to duct chamber exhaust vent(s) to a manifold were calculated for each sterilizer at a facility. (It was assumed that ductwork costs for one of the sterilizers was included in the control device installation cost.)

^bLabor costs developed as \$3.51/ft² of ductwork.

TABLE E-16. DUCTWORK COSTS OF MANIFOLDING
AERATION UNITS TO A GAS/SOLID REACTOR

Item	Cost, \$, 1987	Reference ^{1,3}
<u>Aeration room (AR) ductwork</u>		
A. AR unit to manifold ^a		
1. 32 ft 15-in. diameter, 1/8 in. thick carbon steel	710	Gard, p. 4-19
2. 90° elbow, 15-in. diameter	326	Gard, p. 4-22
3. Labor ^b	481	Richardson, 15-9 p. 2
B. AR manifold		
1. 5 ft 41-in. diameter, 1/8 in. thick carbon steel	318	Gard, p. 4-19
2. Labor ^b	187	Richardson, 15-9 p. 2
C. Manifold to control unit		
1. 67 ft 24-in. diameter, 1/8 in. thick carbon steel	2,480	Gard, p. 4-19
2. 90° elbow, 24-in. diameter costed at \$580/elbow	1,160	Gard, p. 4-22
3. Labor ^{b c}	2,140	Richardson, 15-9 p. 2

^aThese costs were developed for each aeration unit at a facility.

^bLabor costs developed as \$3.51/ft² of ductwork.

^cLabor costs include the cost to concrete core drill (24 in. hole) the aeration room wall at \$784.

E.5 MANIFOLDING COSTS

REFERENCES

1. Richardson Engineering Services, Inc. Process Plant Construction Estimating Standards. 1884.
2. Beall, C., Meeting Minutes: Damas Corp. and Johnson & Johnson. Midwest Research Institute. Raleigh, NC. April 30, 1986. 9 p.
3. Neveril, R., Capital and Operating Costs of Selected Air Pollution Control Systems. GARD, Inc., Niles, IL. Publication No. EPA-450/5-80-002. December 1978.

E.6 COST INDICES

TABLE E-17. CHEMICAL ENGINEERING COST INDICES

	Cost indices	Conversion factor
Scrubbers	352.2 (1987) ^a 392.1 (1989) ^b	0.90
Chlorine filters	352.2 (1987) ^c 344.1 (1987) ^d	1.02
Chemicals	340.8 (1987) ^e 340.0 (1986) ^f	1.002
Operations and maintenance labor	323.8 (1987) ^g 218.8 (1988) ^h	1.48
Disposal of ethylene glycol	323.8 (1987) ⁱ 318.4 (1986) ^j	1.02
Gas/solid reactor or catalytic oxidizer	352.2 (1987) ^k 390.7 (1989) ^l	0.90
Reactant or catalyst replacement	340.8 (1987) ^m 412.0 (1989) ⁿ	0.83
Ductwork	323.8 (1987) ^o 218.8 (1978) ^p	1.48
Disposal of reactant or catalyst	329.8 (1987) ^q 354.2 (1989) ^r	0.93
Labor for installation of ductwork	323.8 (1987) ^s 322.7 (1984) ^t	1.00
Vacuum pumps	433.0 (1987) ^u 418.6 (1986) ^v	1.03

^aReference 1. CE Plant Cost Index, Equipment Machinery, Supports. October 1987 final.

^bReference 2. CE Plant Cost Index, Equipment. September 1989 final.

^cReference 1. Structural Supports and Miscellaneous. October 1987 final.

^dReference 3. Structural Supports and Miscellaneous. February 1986 final.

^eReference 4. Current Business Indicators. October 1987 latest.

^fReference 3. Current Business Indicators. February 1986 previous.

^gReference 1. CE Plant Cost Index, 1987 Annual Index.

^hReference 1. CE Plant Cost Index, 1978 Annual Index.

ⁱReference 1. CE Plant Cost Index, 1987 Annual Index.

^jReference 1. CE Plant Cost Index, 1986 Annual Index.

^kReference 1. CE Plant Cost Index, Equipment, Machinery, Supports. October 1987 final.

^lReference 5. CE Plant Cost Index. Equipment, March 1989 final.

^mReference 6. Current Business Indicators, Producer Prices, Industrial Chemicals, October 1987 (latest).

ⁿReference 5. Current Business Indicators, Producer Prices, Industrial Chemicals, March 1989.

^oReference 5. CE Plant Cost Index, 1987 Annual Index.

TABLE E-17. (continued)

^p Reference 3.	CE Plant Cost Index, 1978 Annual Index.
^q Reference 1.	CE Plant Cost Index, October 1987 final.
^r Reference 3.	CE Plant Cost Index, March 1989 final.
^s Reference 3.	CE Plant Cost Index, 1987 Annual Index.
^t Reference 3.	CE Plant Cost Index, 1984 Annual Index.
^u Reference 4.	CE Plant Cost Index, October 1987 final.
^v Reference 3.	CE Plant Cost Index, February 1986 final.

E.6 COST INDICES

REFERENCES

1. Economic Indicators. Chemical Engineering. McGraw-Hill, Inc., New York, NY. April 25, 1988. p. 9.
2. Economic Indicators. Chemical Engineering. McGraw-Hill, Inc., New York, NY. December 1989. p. 186.
3. Economic Indicators. Chemical Engineering. McGraw-Hill, Inc., New York, NY. June 23, 1986. p. 7.
4. Economic Indicators. Chemical Engineering. McGraw-Hill, Inc., New York, NY. December 7, 1987. p. 7.
5. Economic Indicators. Chemical Engineering. McGraw-Hill, Inc., New York, NY. June 1989. p. 224.

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